UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	
THIS DOCUMENT RELATES TO	**MDL NO. 1456**
State of Montana v. Abbott Labs., Inc., et al., 02-CV-12084-PBS	**Master File No. 01-CV-12257-PBS**
State of Nevada v. American Home Prods. Corp., et al., 02-CV-12086-PBS	**Judge Patti B. Saris**
County of Suffolk v. Abbott Laboratories, Inc., et al., 01-CV-12257-PBS	

EXHIBITS IN SUPPORT OF DEFENDANTS' BRIEF IN RESPONSE TO THE AMICUS CURIAE BRIEFS OF THE UNITED STATES AND THE COMMONWEALTH OF MASSACHUSETTS

EXHIBIT 1

No. 98-1768

In the Supreme Court of the United States

BUCKMAN COMPANY, PETITIONER

v.

PLAINTIFFS' LEGAL COMMITTEE

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Constitution, statutes, regulations and rules:

Statutes, regulations and rules—Continued: Page

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INTEREST OF THE UNITED STATES

This case presents the question whether federal law expressly or impliedly preempts state-law tort claims alleging fraud on the Food and Drug Administration (FDA) during the process of obtaining premarket clearance for certain medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA). The United States has a substantial interest in the resolution of that issue. FDA is responsible for administering the premarket-clearance process for medical devices, and the decision in this case will affect that responsibility. In addition, FDA has issued regulations (21 C.F.R. 808.1) that interpret the FDCA's express preemption provision, 21 U.S.C. 360k(a). At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage in this case, and that brief urged the Court to grant the petition for a writ of certiorari.

STATEMENT

Respondents are persons who claim that they suffered injuries when their physicians implanted orthopedic bone screws into the pedicles of their spines. They allege that

Buckman Company (petitioner) fraudulently obtained clearance from FDA for another company, AcroMed, to market the pedicle screws, and they seek to hold petitioner liable under state law for its alleged role in causing their injuries. The district court granted petitioner's motion to dismiss, holding that respondents' fraud-on-the-FDA claims are preempted by federal law. The court of appeals reversed, holding that such claims are not preempted.

1. a. The FDCA, 21 U.S.C. 301 *et seq.*, regulates food, drugs, cosmetics, and medical devices, and authorizes FDA to enforce its requirements. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplemented the FDCA's medical device requirements. The MDA classifies medical devices into three classes based on the risk they pose to the public and the controls necessary to provide a reasonable assurance of a device's safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. IV 1998). Class I devices present no unreasonable risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful. Such devices are also subject to general controls, but FDA in addition has authority to require that such devices comply with other requirements known as "special controls." 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II). All post-1976 devices are initially deemed Class III devices. 21 U.S.C. 360c(f)(1).

In general, before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" (PMA) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a), (c) and (d) (1994 & Supp. IV 1998); 21 C.F.R. Pt. 814. A "grandfathering" provision permits Class III devices that were on the market before the

MDA's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In the interest of fairness and to prevent "grandfathered" manufacturers from monopolizing the market, Congress also permitted other manufacturers to distribute similar devices by showing through a premarket notification process that they are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). That premarket notification process is known as the "Section 510(k) process," referring to the section of the FDCA codified at 21 U.S.C. 360(k). A device is "substantially equivalent" to a grandfathered device only if, *inter alia*, it has the same "intended use" as that device. 21 U.S.C. 360c(i)(1)(A) (1994 & Supp. IV 1998).

b. FDA regulations set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.F.R. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," 21 C.F.R. 807.87(*l*). The regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted." 21 C.F.R. 807.87(k).

Federal law generally prohibits persons from making false or fraudulent statements in submissions to federal agencies, see 18 U.S.C. 1001 (1994 & Supp. IV 1998), and the FDCA specifically prohibits, "[w]ith respect to any device, the

submission of any report that is required by or under this chapter that is false or misleading in any material respect." 21 U.S.C. 331(q)(2). FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a wide range of remedies and sanctions if it uncovers such fraud, see 21 U.S.C. 332 (injunctive relief); 21 U.S.C. 333(f)(1)(A) (civil money penalties); 21 U.S.C. 334(a)(2)(D) (seizure of the device); 21 U.S.C. 333(a) (criminal prosecution). FDA has established an enforcement policy concerning fraud in premarket submissions that details the kinds of remedies it is likely to pursue. See 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. All lawsuits to enforce the Act's provisions, however, "shall be by and in the name of the United States." 21 U.S.C. 337(a).

c. The MDA contains an express preemption provision, 21 U.S.C. 360k(a), which provides:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) authorizes the Secretary to grant exemptions to the preemption provision in certain circumstances. FDA has issued regulations that interpret the scope of Section 360k(a). Under FDA's interpretation, State or local require-

ments are preempted only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. 808.1(d).

This Court addressed Section 360k's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). The *Medtronic* plaintiffs filed state common law tort actions for injuries caused by a pacemaker that FDA had cleared for distribution under Section 510(k). Plaintiffs asserted causes of action based on defective design, negligent manufacturing, and negligent labeling. The Court first held that Medtronic's compliance with the Section 510(k) premarket clearance process did not preempt plaintiffs' defective design claims, because FDA's clearance did not "require" the pacemaker "to take any particular form for any particular reason." *Id.* at 493; accord *id.* at 513 (O'Connor, J. concurring in part and dissenting in part). The Court next held that Section 360k did not preempt state-law claims in which the duty of care paralleled FDA requirements. *Id.* at 495; accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court explained that common law duties that "parallel" federal requirements are not "different from, or in addition to," the federal requirements. *Ibid.*

Finally, the Court held that Section 360k did not preempt plaintiffs' state-law claims based on negligent manufacturing and labeling. 518 U.S. at 497-502. The Court recognized that FDA regulations impose general manufacturing and labeling requirements. The Court noted, however, that under Section 360k, "federal requirements must be 'applicable to the device' in question, and, according to [FDA] regulations [construing Section 360k], pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" *Id.* at 500. The Court therefore concluded that the "entirely generic" federal manufacturing and labeling requirements did not preempt the *Medtronic* plaintiffs' negligent manufacturing and labeling claims. *Id.* at 501.

2. a. Petitioner, a regulatory consultant, was retained by the AcroMed Corporation to act as its liaison to FDA. Pet. App. 4a. In September 1984, petitioner, on behalf of AcroMed, made a Section 510(k) submission to FDA to obtain marketing clearance for an orthopedic bone screw device known as the Variable Screw Placement (VSP) Spinal Plate Fixation System. *Ibid.* Petitioner's submission stated that AcroMed intended to market the device for use in spinal surgery. *Id.* at 4a-5a. FDA denied the request, finding that the VSP device was a Class III device and was not substantially equivalent to any predicate device marketed before the MDA's enactment. *Id.* at 5a. In September 1985, petitioner filed a second submission for marketing clearance, again stating that the device was intended for use in spinal surgery. *Ibid.* FDA denied the submission on the same ground. *Ibid.*

In December 1985, petitioner and AcroMed made a different attempt to obtain marketing clearance. Pet. App. 5a. They split the VSP device into its two component parts, which they called "nested bone plates" and "cancellous bone screws," and they filed separate Section 510(k) submissions for each component. *Ibid.* Those submissions stated that the devices were intended to be used in long bones of the arms and legs. *Ibid.* In responding to an FDA request for additional information about the devices' intended use, petitioner stated that they "are intended for use in appropriate fractures of long bones of both the upper and lower extremity and such other flat bones (as in the fractured pelvis)." J.A. 16. In February 1986, FDA granted marketing clearance for AcroMed's bone plates and screws for that stated purpose. Pet. App. 5a.

b. Respondents are plaintiffs who filed lawsuits alleging that they were injured when their doctors inserted the assembled VSP device into their spines. Pet. App. 1a. More than 2300 individual lawsuits were brought against multiple defendants, and those suits were consolidated for pre-trial

proceedings in the Eastern District of Pennsylvania pursuant to the multi-district litigation statute, 28 U.S.C. 1407 (1994 & Supp. IV 1998). Pet. App. 1a. The only count against petitioner is one that respondents call "fraud on the FDA." *Id.* at 5a. That count asserts that petitioner intentionally and falsely represented to FDA that the devices for which it sought clearance were "intended for use" in the long bones, when, in fact, the devices were "intended exclusively for use in the spine." J.A. 15-16. Respondents further allege that FDA did not know that the devices were intended exclusively for use in the spine, and that if petitioner had not made false statements about their intended use, FDA would not have cleared the devices for marketing, the devices would not have been sold, and respondents would not have been injured. J.A. 21. Respondents' claim does not depend on any allegation that the device itself was defective under state law or had been manufactured or labeled in a manner that was negligent or illegal under state law.

c. The district court dismissed the fraud-on-the-FDA claims on the ground that they were expressly preempted under 21 U.S.C. 360k. Pet. App. 53a. The district court reasoned that the MDA "does not permit courts to 'perform the same function initially entrusted to the FDA,'" *id* at 49a, and that FDA is in the "best position" to decide whether a manufacturer has "withheld material information from the agency and, if so, [to determine] the appropriate sanction," *id.* at 50a. After this Court decided *Medtronic*, respondents asked the district court to reinstate their fraud-on-the-FDA claims. *Id.* at 7a. The district court concluded that *Medtronic* foreclosed a finding of express preemption. *Id.* at 40a. It nevertheless refused to reinstate respondents' claims on the ground that they constituted an impermissible attempt to assert a private right of action for a violation of the MDA. *Id.* at 36a-40a.

3. A divided panel of the court of appeals reversed. Pet. App. 1a-32a. The court first held that respondents' fraud-on-

the-FDA claims are not expressly preempted, because there is neither a "federal 'requirement' 'applicable to the device' at issue," nor "a state 'requirement' 'with respect to' that device." *Id.* at 13a. The court further held that the "state common law relied upon [by respondents] does not impose any obligation on [petitioner] inconsistent with federal law," because "18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency and 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed to be truthful." *Ibid.* The court of appeals also rejected the district court's conclusion that fraud-on-the-FDA claims constitute an impermissible attempt to obtain a private right of action for violations of the MDA. *Id.* at 13a-17a. The court concluded that such reasoning is inconsistent with *Medtronic*. *Id.* at 16a.

The court of appeals also held that respondents' fraud-on-the-FDA claims are not impliedly preempted. Pet. App. 18a. The court saw "no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and "common law fraudulent misrepresentation claims." *Ibid.* Finally, the court rejected petitioner's contention that a statement of intended use refers to the use for which an applicant seeks market clearance. *Id.* at 22a-24a. The court held that a statement of intended use refers to an applicant's marketing intentions. *Id.* at 22a-23a. The court therefore concluded that, if AcroMed intended at the time of the application to market its device solely for use in the spine, petitioner's statement that the device was intended for use in the long bones would have constituted a material misrepresentation. *Id.* at 23a-24a.

Judge Cowen dissented. Pet. App. 25a-32a. Judge Cowen concluded that fraud-on-the-FDA claims conflict with federal law because they "greatly distort the penalty scheme established by the statute." *Id.* at 28a. In particular, the "penalties attached to a violation of the FDA's regulations will

often be substantially increased, and enforcement of violations will no longer be controlled by the FDA's prosecutorial discretion." *Ibid.* Judge Cowen also concluded that fraud-on-the-FDA claims conflict with federal law because they permit juries to impose "[m]assive liability" when FDA "would not find any misconduct." *Id.* at 31a.

SUMMARY OF ARGUMENT

I. Respondents' fraud-on-the-FDA claims are not expressly preempted by FDA's Section 510(k) disclosure requirements. Under *Medtronic*, express preemption occurs only when (1) the federal requirement is specific, and (2) the counterpart state requirement is different from, or in addition to, that specific federal requirement. Neither of those prerequisites for express preemption is present here.

First, FDA's Section 510(k) disclosure requirements are not specific. They are stated in general terms, and they apply to all devices that must undergo the Section 510(k) clearance process, not just pedicle screw devices. Second, respondents' common law theory of liability does not impose a duty that is different from, or in addition to, the applicable federal requirements. Federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance. Respondents' claim that petitioner falsely represented to FDA that its devices were intended for use in the long bones, when, in fact, they were intended exclusively for use in the spine, does not impose any requirement that is different from an applicable federal requirement.

II. Respondents' fraud-on-the-FDA claims nonetheless are impliedly preempted by federal law. When Congress legislates in a field of traditional state concern, there is a presumption against preemption. That presumption applied to the defective design, negligent manufacturing, and failure to warn claims at issue in *Medtronic*. Respondents' claims, however, focus on an entity's obligations to truthfully dis-

close information to a federal regulatory agency. That field is not one that States have traditionally occupied; instead, it is one of preeminent federal concern. Under this Court's cases, when state law intrudes on an area of preeminent federal concern, the presumption against preemption disappears, and the danger of a fatal conflict significantly increases.

Applying the preemption analysis that is appropriate when state law intrudes on an area of preeminent federal concern, respondents' fraud-on-the-FDA claims conflict with federal law. In particular, they conflict with the important federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action.

Respondents' fraud-on-the-FDA claims also conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices. Respondents' claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA.

Fraud-on-the-FDA claims also invite highly intrusive discovery concerning federal agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. Such claims therefore pose a real danger of diverting FDA's resources from the important health mission that Congress

has assigned to it and of distorting FDA's internal decision-making process.

ARGUMENT

I. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE NOT EXPRESSLY PREEMPTED

Petitioner contends (Pet. 26-27) that respondents' fraud-on-the-FDA claims are expressly preempted. In particular, petitioner argues that the federal requirement that an applicant for Section 510(k) marketing clearance submit information concerning a device's "intended use" preempts respondents' fraud-on-the-FDA claims. Under the MDA, however, express preemption occurs only when there is (1) a federal "requirement applicable to the device," and (2) the state requirement is "is different from, or in addition to," that federal requirement. 21 U.S.C. 360k(a). Neither of those prerequisites for express preemption is present here.

A. FDA's Disclosure Requirements Are Not Specific

In *Medtronic*, the Court held that federal "requirement[s]" are "applicable to the device" within the meaning of the MDA's express preemption provision only when they are "'applicable to the device' in question," 518 U.S. at 500, and, in accordance with FDA regulations, only when they are "'specific counterpart regulations' or 'specific' to a 'particular device,'" *ibid.* (quoting 21 C.F.R. 808.1(d)). Federal requirements therefore can have preemptive force under Section 360k(a) when "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501. Federal requirements do not have a preemptive effect under Section 360k(a), however, when they "reflect important but entirely generic concerns about device regula-

tion generally." *Id.* at 501-502; see also *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment).

Medtronic establishes a sensible and administrable line for determining the kind of federal requirements that can have preemptive force under Section 360k(a). For example, FDA's requirements concerning hearing aids (21 C.F.R. 801.420, 801.421), cables and leads (21 C.F.R. 898), impact-resistant lenses (21 C.F.R. 801.410), and devices containing natural rubber (21 C.F.R. 801.437) preempt counterpart state requirements that are different from, or in addition to, those requirements. Those federal requirements are stated with specificity and apply to a specific device or set of devices. In contrast, as the Court explained in *Medtronic*, FDA's general manufacturing and labeling requirements do not have preemptive force. 518 U.S. at 501. Those requirements are stated at a high level of generality and apply to all devices.

Under the interpretation of the express preemption provision adopted in *Medtronic*, the requirement that an applicant submit information concerning a device's "intended use" does not have preemptive force. That requirement is stated in general terms, and it applies to all devices that must undergo the Section 510k clearance process, not just pedicle screw devices. See 21 C.F.R. 807.87(e). Thus, like the general manufacturing and labeling requirements at issue in *Medtronic*, the statement of intended use required of applicants in the Section 510k process is not a "'specific counterpart regulation[]' or 'specific' to a 'particular device.'" *Medtronic*, 518 U.S. at 500 (quoting 21 C.F.R. 808.1(d)). It is therefore not the kind of federal requirement that can have a preemptive effect under the MDA's express preemption provision.[1]

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[1] As we explain in our amicus brief at the petition stage (at 10-11 n.4), Section 360k(a) does preempt a specific duty of care that is made applica-

B. Respondents' Fraud-On-The-FDA Claims Parallel Federal Requirements

Even if the general duty to provide information to FDA about a product's "intended use" were the kind of federal requirement that could have a preemptive effect under Section 360k(a), respondents' fraud-on-the-FDA claims would still not be expressly preempted. As construed in *Medtronic*, Section 360k does not deny a State "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. Such common law duties are not "different from, or in addition to," federal requirements within the meaning of Section 360k. *Ibid.*

Respondents' sample complaint includes allegations that petitioner committed common law fraud when it falsely informed FDA that AcroMed's devices were intended for use in long bones when, in fact, they were intended exclusively for use in the spine. Pet. App. 8a-9a; J.A. 15-16. Since federal law requires a manufacturer to truthfully disclose a device's intended use in its submission for Section 510(k) clearance (see 21 U.S.C. 331(q)(2); 18 U.S.C. 1001; 21

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ble to a device through application in litigation of a State's common law of torts, if that requirement is different from, or in addition to, a specific requirement imposed by FDA. It does not follow from the fact that a general *state* tort duty may be preempted as applied in a particular case that the existence of general *federal* standards have preemptive force. The Court rejected that contention in *Medtronic*. 518 U.S. at 501-502; *id.* at 506-507 (Breyer, J., concurring in part and concurring in the judgment). Similarly, the fact that a device has been cleared by FDA through the Section 510(k) process does not mean that any general rules and duties governing that process have thereby been made "specific" to the device. At most, FDA would have determined only that any preexisting requirements governing the process (whether general or "specific") were satisfied. In any event, there is no indication in this case that FDA determined when it cleared the device under Section 510(k) that petitioner and AcroMed had satisfied all applicable duties of disclosure.

C.F.R. 807.87(e); 21 C.F.R. 807.87(k)), respondents' common law fraud theory parallels the applicable federal requirements. It is therefore not "different from, or in addition to," the applicable federal requirements within the meaning of Section 360k(a).

Petitioner argues (Pet. 27; Reply Br. Pet. Stage 9-10) that respondents' common law theory imposes a requirement that is different from the applicable federal requirement because, under federal law, "intended use" refers to the use set forth in the labeling, while respondents' common law theory equates intended use with a manufacturer's subjectively desired off-label uses. Petitioner's contention misreads both the applicable federal standards and the allegations in respondents' complaint.

Under FDA's regulations, the "intended use" of a medical device is defined by the "objective intent of the persons legally responsible for the labeling of [the] device[]," and objective intent "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." 21 C.F.R. 801.4. Because objective intent is determined in part by reference to a manufacturer's "expressions," a device's "labeling" is relevant in determining a device's intended use. 21 C.F.R. 801.4. But a device's labeling is not the exclusive source for determining intended use. Also relevant are, *inter alia*: (1) "advertising matter," (2) a manufacturer's "oral or written statements," (3) the manufacturer's "knowledge" that a product is "offered and used for a purpose for which it is neither labeled nor advertised," and (4) the manufacturer's "knowledge" of facts that would give him "notice" that a product "is to be used" for purposes other than those for which the manufacturer offered it. 21 C.F.R. 801.4. See also 21 C.F.R. 801.5 (discussing adequate directions for use of a device for its intended use).

Thus, when FDA seeks from an applicant a statement of a device's intended use, it is not simply asking for the use that

will appear on the labeling. It is asking for the intended use that will be revealed by all the manufacturer's "expressions" and "the circumstances surrounding" the device's "distribution." 21 C.F.R. 801.4. Under the regulations, a manufacturer is not required to disclose every foreseeable use of a device that it secretly desires. Physicians often use medical devices for purposes that are not identified in the labeling, and manufacturers may seek Section 510(k) clearance for the use identified in the labeling without setting forth every possible off-label use to which the device might be put after it reaches the market. But whatever may be the full scope of a manufacturer's duty to disclose possible uses of the device beyond those stated in the labeling the manufacturer has submitted, when, at the time of the application, a manufacturer plans to promote and distribute a device exclusively for one use, it must disclose to FDA that intended use. A statement to FDA that the device has a different intended use would be false and misleading. The intended use stated in the premarket notification must be a bona fide use; it cannot be a pretext calculated to clear the device for distribution for other uses.[2]

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[2] That conclusion is not affected by the 1997 amendments to the FDCA. Those amendments were not in effect at the time of petitioner's alleged misconduct. In any event, the amendments do not alter the analysis for devices subject to the Section 510(k) process after they were enacted. Under 21 U.S.C. 360c(i)(1)(A), as amended in 1990, a device can be found to be substantially equivalent to a pre-1976 device only if it "has the same intended use as the predicate device." The 1997 amendments provide only that (for a period of five years), in making a "substantial equivalence" determination, FDA's determination concerning a device's "intended use * * * shall be based upon the proposed labeling." 21 U.S.C. 360c(i)(1)(E)(i) (Supp. IV 1998). That provision does not relieve manufacturers of their obligation under 21 C.F.R. 807.87(e), 807.87(k) and 21 U.S.C. 331(q)(2) to truthfully inform FDA of a device's "intended use" as that term is defined in FDA's "intended use" regulation, 21 C.F.R. 801.4. The manufacturer must continue to furnish proposed labeling that accurately reflects the device's intended use, and FDA then determines

Respondents' sample complaint includes allegations that petitioner engaged in just such misleading conduct. Respondents do not claim that AcroMed intended to market its devices for use in the long bones, but secretly hoped that they would be used in spinal surgery as well. Rather, respondents claim that, while petitioner represented to FDA in its Section 510(k) submission that AcroMed's devices were intended to be used in the long bones, in fact, AcroMed planned to promote and distribute the devices exclusively for use in the spine. J.A. 15-16. That common law theory of liability does not rest on the imposition of a duty that is "different from" or "in addition to" federal requirements. Instead, that common law theory is consistent with the duties imposed by applicable federal requirements. It is therefore not expressly preempted.

II. RESPONDENTS' FRAUD-ON-THE-FDA CLAIMS ARE IMPLIEDLY PREEMPTED

The absence of express preemption, however, does not exhaust the preemption inquiry. An express preemption provision "does not bar the ordinary working of conflict pre-

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substantial equivalence based on the proposed labeling. The amendments also authorize FDA to require a statement in a device's labeling concerning "a use of the device not identified in the labeling" if FDA determines "that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling" and "such use could cause harm." 21 U.S.C. 360c(i)(1)(E)(i)(I) and (II) (Supp IV 1998). That statutory authority confirms that a device's intended use may be determined from evidence other than a device's proposed labeling and that FDA is required to confine its inquiry to the intended use identified in the proposed labeling only when it makes a substantial equivalence determination. That statutory authority concerning other potentially harmful intended uses also underscores why a manufacturer seeking Section 510(k) clearance for a device must disclose all intended uses of the device, not merely those set forth in whatever proposed labeling the manufacturer chooses to submit in the Section 510(k) clearance process.

emption principles." *Geier* v. *American Honda Motor Co.*, 120 S. Ct. 1913, 1919 (2000). Those principles preclude respondents' fraud-on-the-FDA claims.

A. Fraud-On-The-FDA Claims Intrude On An Area Of Preeminent Federal Concern, And Are Therefore Subject To A More Stringent Conflict Preemption Analysis

1. When Congress legislates "in a field which the States have traditionally occupied," preemption analysis begins "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485. That assumption "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Ibid.* The *Medtronic* plaintiffs' claims of defective design, negligent manufacturing, and negligent failure to warn all implicated core areas of traditional state concern. The Court therefore began its analysis in *Medtronic* with a "presumption" that Congress did not intend to preempt those claims. *Ibid.*

The situation here is fundamentally different. Respondents' fraud-on-the-FDA claims do not depend on any showing that the device had a defective design, was negligently manufactured, or did not bear adequate warnings under state law. Pet. App. 8a-9a. Instead, respondents simply contend that, but for petitioner's alleged misrepresentations to FDA, the agency would not have cleared the device for marketing, the device would not have been marketed, and they would not have been injured. *Ibid.* Respondents' claim therefore does not focus on the device itself, on the manner in which it was designed, produced, and distributed, or on a State's legitimate interest in those subjects. It focuses,

rather, on the relationship between the federal government and the entities it regulates.

The field involving an individual's obligations to the federal government, and, more particularly, an individual's obligation to provide accurate information to a federal regulatory agency, is not one "which the States have traditionally occupied." *Medtronic*, 518 U.S. at 485. Unlike the traditional common law torts at issue in *Medtronic*, the newly fashioned state-law tort of committing fraud on a federal regulatory agency has no existence that is independent of the federal statutes that establish federal regulatory agencies and require regulated entities to make certain disclosures to those federal agencies. In this case, for example, a holding that fraud-on-the-FDA claims are preempted would not eliminate any claim that existed under state law before the MDA was enacted. Conversely, the field involving an individual's obligation to provide accurate information to a federal regulatory agency is one in which there is an overriding and longstanding federal interest. If federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how to sanction those who fail to provide such information.

In enacting the 1934 amendment to 18 U.S.C. 1001, Congress recognized the paramount need of federal regulatory agencies to receive accurate information from entities they regulate. The 1918 version of Section 1001 had prohibited false statements to government officials made for the purpose of cheating the government out of property or money. That restricted scope "became a serious problem with the advent of the New Deal programs in the 1930s." *United States* v. *Yermian*, 468 U.S. 63, 80 (1984) (Rehnquist, J., dissenting). Because the new regulatory agencies relied heavily on the reports filed by regulated entities to ensure compliance, the filing of false reports could readily defeat the

agency's regulatory objectives. *United States* v. *Gilliland*, 312 U.S. 86, 92-93 (1941). To address that concern, Congress amended Section 1001 to prohibit the making of any false statement or the filing of any false writing or document on any matter within the jurisdiction of any department or agency of the United States. *Ibid.* That amendment confirms the importance that federal law places on a regulatory agency's ability to obtain accurate information from those it regulates.

2. Because respondents' fraud-on-the-FDA claims implicate an area of paramount federal interest, they are subject to a more stringent conflict preemption analysis. Under this Court's cases, when state law implicates an area of preeminent federal concern, the presumption against preemption disappears and the likelihood of a fatal conflict between state and federal law significantly increases.

For example, in *Boyle* v. *United Techs. Corp.*, 487 U.S. 500 (1988), the Court noted that, while "[i]n most fields of activity," the Court has "refused to find federal pre-emption of state law in the absence of either a clear statutory prescription * * * or a direct conflict between federal and state law," in areas involving "unique federal interests", the Court has more readily determined that state law is pre-empted. *Id.* at 504. The Court explained that the presence of a "unique federal concern changes what would otherwise be a conflict that cannot produce pre-emption into one that can." *Id.* at 508. Applying that analysis, the Court held that design defect suits against government contractors implicate unique federal interests that require the displacement of state law. *Id.* at 511-512. In reaching that conclusion, the Court noted that such suits border on two areas that it had previously found to involve uniquely federal interests: the obligations and rights of the United States under its contracts, which are governed exclusively by federal law, and the civil liability of federal officers for actions taken in the course of their official duty, which in many contexts is con-

trolled by federal law. *Id.* at 505. Just as federal law presumptively defines the duties owed by federal employees and contractors to the federal government, so too here federal law presumptively defines the duties owed to the federal government by entities regulated by the federal government. Cf. *Hancock* v. *Train*, 426 U.S. 167, 178-179 (1976).

Moreover, in *Boyle*, the plaintiff sought to hold the manufacturer liable for injuries caused by a product that allegedly was defective—a field generally subject to state law—and that state law was displaced only to the extent necessary to give effect to the countervailing federal interests.[3] Here, by contrast, respondents' fraud-on-the-FDA count does not depend on any claim that the product itself was independently defective under state law or on any claim that the distribution of the product independently violated any duty owed under state law. The concerns about the displacement of state law in *Boyle* are therefore largely inapplicable here.

In *Pennsylvania* v. *Nelson*, 350 U.S. 497 (1956), the Court held that federal sedition laws preempt comparable state prohibitions. The Court reasoned that the federal sedition laws "touch a field in which the federal interest is so dominant that the federal system [must] be assumed to preclude enforcement of state laws on the same subject." *Id.* at 504. The Court further explained that "[s]edition against the United States is not a *local* offense. It is a crime against the *Nation*. * * * It is not only important but vital that such prosecutions should be exclusively within the control of the Federal Government." *Id.* at 505.

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[3] In fashioning the scope of the government-contractor defense to liability under state law in those circumstances, the Court in *Boyle* relied on the discretionary function exemption under the Federal Tort Claims Act, 28 U.S.C. 2680(a), which exempts the United States from liability for performing the discretionary function of selecting an appropriate design. The Court held that to subject a federal contractor to liability for a design that was selected by the federal agency would undermine that exemption. 487 U.S. at 511-512.

And, in *United States* v. *Locke*, 120 S. Ct. 1135, 1151-1152 (2000), the Court held that Coast Guard regulations concerning the reporting of marine casualties preempted a state regulation that imposed similar requirements. The Court reasoned that the "assumption" of non-preemption does not apply "in an area where there has been a history of significant federal presence," *id.* at 1147, that maritime commerce constitutes such an area, *id.* at 1148, and that, in an area of preeminent federal concern, even state laws that mirror federal requirements can conflict with the intent to create "a workable, uniform system," *id.* at 1151.

B. Fraud-On-The-FDA Claims Conflict With The Important Federal Interest In Permitting FDA To Decide For Itself Whether It Has Been Defrauded, And, If So, What Remedy To Seek

Applying the analysis that is appropriate in cases involving an area of preeminent federal concern, respondents fraud-on-the-FDA claims are preempted. The FDCA establishes a comprehensive scheme to regulate the information that an entity must submit to FDA, and respondents' fraud on the FDA claims conflict with the strong federal interest in uniform enforcement of that comprehensive scheme.

1. FDA has issued regulations that set forth the information that an applicant must supply in order to obtain clearance under Section 510(k). 21 C.F.R. 807.87. The manufacturer must furnish, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 C.F.R. 807.87(e), "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," 21 C.R.F. 807.87(f), and "[a]ny additional information regarding the device requested by [FDA] that is necessary for [FDA] to make a finding as to whether or not the device is substantially equivalent to a device in com-

mercial distribution," 21 C.F.R. 807.87(*l*). FDA has issued guidance on how to supply the information required by its regulations. See *Premarket Notification 510(k): Regulatory Requirements for Medical Devices, http://www.fda.gov /cdrh/manual/510kprt1.html.* FDA's regulations also require each person submitting a premarket notification to state that, "to the best of his or her knowledge," all "data and information" are "truthful and accurate" and that "no material fact has been omitted," 21 C.F.R. 807.87(k), and the FDCA specifically prohibits, "[w]ith respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect," 21 U.S.C. 331(q)(2).

The FDCA also contains a comprehensive scheme for enforcing those obligations. FDA has authority to investigate suspected fraud by a person seeking market clearance, 21 U.S.C. 372; 21 C.F.R. 5.35, and may pursue a variety of remedies and sanctions if it uncovers such fraud, including injunctive relief, 21 U.S.C. 332, civil money penalties, 21 U.S.C. 333(f)(1)(A), seizure of the device, 21 U.S.C. 334(a)(2)(D), and criminal prosecution, 21 U.S.C. 333 (a), 18 U.S.C. 1001 (1994 & Supp. IV 1998). FDA has adopted an enforcement policy concerning fraud and untrue statements of material facts in premarket submissions. 56 Fed. Reg. 46,191, 46,199-46,200 (1991). Under that policy, when FDA finds that a submission contains fraudulent and unreliable data, it may withdraw clearance of a device cleared for marketing under Section 510(k) and seek voluntary corrective action from the submitter, such as removal of the persons involved in the wrongdoing from substantive responsibility for matters under FDA's jurisdiction. *Ibid.* Any citizen who believes that a submitter has committed fraud may petition FDA to take administrative action. 21 C.F.R. 10.30. But there is no private right of action to enforce the FDCA's prohibitions. *Medtronic*, 518 U.S. at 487. FDA and the United States have exclusive authority to determine

how the provisions of the Act should be enforced. See 21 U.S.C. 337(a).

2. Respondents' fraud-on-the-FDA claims conflict with that comprehensive federal scheme for regulating the information that a regulated entity must submit to FDA. In particular, they conflict with the strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what statutorily authorized remedy to seek. That conflict manifests itself in three ways.

First, fraud-on-the-FDA claims would permit juries in different States to reach judgments that differ from FDA's concerning whether an entity has actually committed fraud on the FDA. As Judge Cowen observed in his dissenting opinion in this case, juries could "impose massive liability," when FDA "would not find any misconduct." Pet. App. 31a. Even if juries in different States applied the same substantive standards as FDA, it would not eliminate that conflict. As this Court has explained, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953).

Second, allowing fraud-on-the-FDA claims would "distort the penalty scheme established by the statute." Pet. App. 28a (Cowens, J., dissenting). While the FDCA contains a wide range of possible remedies for fraud on the FDA, neither compensatory relief nor punitive damages is among them. "[S]ince remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy * * * which has been withheld from the [FDA], * * * accentuates the danger of conflict." *San Diego Bldg, Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959); see also *Crosby* v. *National Foreign Trade Council*, 120 S. Ct. 2288, 2298 (2000) ("[C]onflict is imminent when two separate remedies are brought to bear on the same activity.")

Third, if common law fraud-on-the-FDA claims are permitted, it would interfere with FDA's discretion to decide which of the statutorily prescribed remedies, if any, to pursue. The FDCA allows FDA to pursue the remedies that, in FDA's judgment, best fit the violation and the overall purposes of the Act. See *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). For example, FDA may decide in a particular case in which fraud has been identified that the established health benefits of the device concerned counsel against removing the device from the market or imposing a severe penalty, and that removing the persons involved in the wrongdoing from responsibility for submissions is a more appropriate sanction. If fraud-on-the-FDA claims may be brought, the juries in 50 States could substitute their judgments for FDA's as to the appropriate sanction. Since fraud on the FDA "is not a *local* offense," but an offense against the United States, it is "vital" that enforcement "should be exclusively within the control of the Federal Government." *Nelson*, 350 U.S. at 505.

3. Because there is a strong federal interest in permitting FDA to decide for itself whether it has been defrauded, and, if so, what sanction is appropriate, state regulation of fraud on the FDA is preempted. If a State attempted to establish its own administrative agency to monitor fraud on the FDA, and devised its own set of sanctions for punishing such fraud, the conflict between that system and the federal interest in uniform enforcement would be apparent. That sharp conflict is not lessened simply because the state scheme for regulating fraud on the FDA takes the form of a common law cause of action. See *Garmon*, 359 U.S. at 247 ("The obligation to pay compensation" is "a potent method of governing conduct and controlling policy."). On the contrary, permitting private prosecution of fraud on the FDA only exacerbates the conflict, since private parties have no obligation to take into account the public interest before filing suit. *Nelson*, 350 U.S. at 507-508.

C. Respondents' Fraud-On-The-FDA Claims Conflict With FDA's Market Clearance Decision

Respondents' fraud-on-the-FDA claims are preempted for another reason. They conflict with FDA's decision to grant market clearance for AcroMed's pedicle screw devices.

1. Under basic principles grounded in the Supremacy Clause, a federal administrative decision that has neither been rescinded by the agency nor set aside by a federal court in accordance with the procedures for review established by Congress has a preemptive effect. A State may not provide a common law cause of action that fails to give effect to such a decision. *Arkansas La. Gas Co* v. *Hall*, 453 U.S. 571 (1981) (*Arkla*); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981).

Arkla and *Kalo Brick* illustrate the preemptive effect of federal administrative decisions on state common law causes of action. In *Arkla*, Hall contracted to sell natural gas to Arkla at a specified rate, but the contract provided that, if Arkla purchased natural gas from another party at a higher rate, Hall would be entitled to that rate. 453 U.S. at 573. Hall filed the agreed-upon rate with the Federal Power Commission, and the Commission authorized the sale of gas at that rate. *Id.* at 574. Some years later, Arkla purchased gas from another party at a higher rate, but did not inform Hall of that fact or increase its payments to Hall. When Hall learned of Arkla's higher payments to the other party, he filed a state court breach of contract action, and the Louisiana Supreme Court awarded as damages the difference between what Arkla paid Hall and what it paid to the third party. *Id.* at 574.

This Court reversed, holding that the state contract action was preempted by the Commission's approval of Hall's filed rate. *Arcla*, 453 U.S. at 578-579. The Court reasoned that the "filed rate doctrine" forbids a regulated entity to charge rates for its services other than those filed with the

appropriate federal regulatory agency, and that it would undermine the federal scheme to allow a state court to award as damages a rate never filed with the Commission and never found by the Commission to be reasonable. *Id.* at 578-579. The Louisiana Supreme Court's determination that the Commission would have approved the higher rate as reasonable had it known about the circumstances of the case did not eliminate the conflict, *id.* at 580-581, since "under the filed rate doctrine, the Commission alone is empowered to make that judgment, and until it has done so, no rate other than the one on file may be charged," *id.* at 581. By awarding damages based on an assumption about what the Commission might have done, the Louisiana Supreme Court had "usurped a function that Congress ha[d] assigned to a federal regulatory body." *Id.* at 582; see also *Nantahala Power & Light Co.* v. *Thornburg*, 476 U.S. 953, 963-964 (1986).

In *Kalo Brick*, the Interstate Commerce Commission approved a rail carrier's request to abandon service on a particular rail line. 450 U.S. at 314-315. Rather than seeking judicial review of the Commission's decision, a shipper who used that line asserted a common law tort action against the rail carrier for damages resulting from the abandonment of service. *Id.* at 315. The Court held that the common law tort action was preempted by the Commission's decision. *Id.* 324-327. The Court rejected the argument that the state tort remedy merely complemented the federal abandonment remedy. *Id.* at 324. The Court reasoned that the Act grants "exclusive discretion" to the Commission to decide whether a carrier should be permitted to abandon service on a line, and that it would be contrary to that feature of the Act "to permit litigation challenging the lawfulness of the carrier's actions to go forward when the Commission has expressly found them to be reasonable." *Id.* at 326.

2. Under the principles applied in *Arkla* and *Kalo Brick*, respondents' fraud-on-the FDA claims are preempted. FDA granted market clearance for AcroMed's pedicle screws, and

that decision has not been rescinded by FDA or set aside by a federal court in accordance with the procedures for judicial review established by Congress. Accordingly, under *Arkla* and *Kalo Brick*, FDA's clearance decision is entitled to respect under the Supremacy Clause, and no State may provide a common law cause of action that fails to give effect to that decision.

Respondents' fraud-on-the-FDA claims, however, fail to give effect to FDA's market clearance decision. Those claims proceed on the assumption that AcroMed should not have received market clearance for its pedicle screws from FDA, and that respondents should receive damages as if the marketing of the pedicle screws cleared by FDA was unlawful under the FDCA. C.A. App. A63. Those assumptions directly conflict with FDA's decision clearing the devices for marketing under the FDCA. Litigation "challenging the lawfulness" of petitioner's actions in obtaining market clearance for the devices under the FDCA cannot "go forward" when FDA has "expressly found" that the devices should be cleared for marketing under that Act. *Kalo Brick*, 450 U.S. at 326. Respondents' assertion that FDA would not have cleared the devices had it known that petitioner misrepresented their intended use, moreover, does nothing to avert the conflict. FDA "alone is empowered" to decide whether a device should be cleared for marketing under the FDCA, and, by seeking damages based on an assumption concerning what FDA "might have done," respondents seek to "usurp[] a function that Congress has assigned to a federal regulatory body." *Arkla*, 453 U.S. at 581-582.[4]

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[4] Respondents' claims do not conflict with FDA's 1998 decision to classify and reclassify pedicle screw spinal systems for certain uses as Class II devices. FDA's classification and reclassification decision occurred after the underlying events at issue here (see Pet. App. 5a), and it was not intended to legitimize conduct that was unlawful at the time it occurred. 63 Fed. Reg. 40,025, 40,037-40,038 (1998). We also note that FDA classified and reclassified pedicle screw spinal systems as Class II devices only

D. Fraud-On-The-FDA Claims Would Result In Undesirable Practical Consequences

A holding that fraud-on-the-FDA claims are not preempted would also produce undesirable practical consequences. Absent an applicable privilege, *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 150-151 (1975), such claims would invite highly intrusive inquiries into FDA's internal deliberations. For example, respondents assert, as necessary elements of liability, that FDA did not know about the true intended use of the device in question; that FDA relied on petitioner's misrepresentation about that intended use; and that FDA would not have cleared the device for marketing in the absence of petitioner's alleged fraud. Pet. App. 8a-9a.

In litigating those issues, the parties would very likely seek discovery from FDA concerning agency officials' states of mind and the courses of action that agency decisionmakers might have taken under various hypothetical scenarios. It is the position of the United States that employees of the federal government are immune from third-party subpoenas issued in private litigation, that testimony must be sought under an agency's *Touhy* regulations, see generally *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951), and that an agency's denial of a request for testimony by agency employees is subject to review only in federal court and only under the "arbitrary" or "capricious" standard of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). The lower federal courts, however, have taken divergent views on issues concerning third-party subpoenas issued by a federal court to federal employees. Compare, *e.g.*, *Comsat Corp.* v. *National Science Foundation*, 190 F.3d 269, 277-278 (4th Cir. 1999) (applying APA standard), with *Exxon Shipping Co.* v.

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for certain spinal uses, and it imposed four "special controls" for those uses. *Id.* at 40,027, 40,034-40,038. The record in this case does not address whether the devices that AcroMed marketed satisfied those limitations.

United States Dep't of Interior, 34 F.3d 774, 778-780 (9th Cir. 1994) (agency must produce evidence in response to a federal court subpoena, subject only to court's discretion to limit discovery under Fed. R. Civ. P. 26 and 45). Regardless of how that issue is ultimately resolved, widespread litigation could be expected on whether testimony and other evidence could be secured from FDA. This multidistrict litigation alone involves thousands of plaintiffs in more than 2000 cases that could be tried in several dozen different judicial districts. The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting FDA's resources from the important health mission that Congress has assigned to it and for distorting FDA's internal decisionmaking processes.

Nor would the undesirable consequences of fraud-on-the-FDA claims abate if the courts ultimately accept the government's position on when its officials can be required to testify. Parties would still be free to challenge any refusal to testify under the Administrative Procedure Act, and would retain every incentive to do so. And, in cases in which a government claim of privilege is sustained, a jury could only speculate about the crucial issues in the case. Such speculation would increase the danger that the jury's decision would conflict with FDA's judgment concerning whether it was defrauded and, if so, what should be done.

Permitting state-law suits for fraud on a federal agency could also distort the behavior of regulated entities. Those entities base their behavior largely on their understanding of how federal law has been applied in the past and how it will likely be applied in the future. If a regulated entity knows that juries applying the tort law of any one of the 50 States will play a central role in interpreting the entity's duties to the federal government, that concern could cause it to alter its behavior in unpredictable ways that may well be inconsistent with the efficient administration of the federal regulatory scheme. For example, if, in order to avoid a risk

that a jury in one of 50 States might conclude that they have withheld relevant information, regulated entities began to flood FDA with information that FDA does not need, it could significantly complicate the clearance process.

Fraud-on-the-FDA claims therefore pose a real danger of making it more difficult for FDA to perform its central mission of protecting the public health. That consequence can be avoided by a holding that such claims are impliedly preempted.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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SEPTEMBER 2000

EXHIBIT 2

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. [redacted] price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as [redacted] numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/l/90-9/30/90 quarter for purposes of computing the AMP as of 10/l/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free go[redacted]olu[redacted]unts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to assure that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price, and, in the case of Single Source and Innovator Multiple Source Drugs, the [redacted] Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under II(b), [redacted]0,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISP[redacted]RESOLUTION [redacted]EDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION PROCEDURE FOR DRUG ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be interpreted in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ _____
Date

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____
(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____

EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date MAY 8 1998

From June Gibbs Brown
Inspector General

Subject Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached is our final report of the Department of Health and Human Services, Office of Inspector General entitled, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs." Enactment of a legislative change requiring that rebates be based on average wholesale price (AWP) would have resulted in about $1.15 billion in added Medicaid rebates for the Calendar Years 1994 through 1996 for only the top 100 drugs for each calendar year used in our analysis. Requiring manufacturers to pay Medicaid drug rebates based on AWP would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate average manufacturers price (AMP);
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid's reimbursement for drugs at the pharmacy level; and
- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

We recommended that the Health Care Financing Administration (HCFA) develop and submit a legislative proposal to the Congress that would require drug manufacturers participating in the Medicaid outpatient prescription drug program to pay Medicaid drug rebates based on AWP.

In responding to our draft report, HCFA disagreed with our recommendation for development and submission of a legislative proposal to Congress on this issue. The HCFA does not believe that such legislation is feasible at this time. A statement was made by HCFA, however, that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. However, the response stated that the calculation of AWP itself needs to be examined, and HCFA is planning a comprehensive study of AWP.

We appreciate HCFA's position of not wanting to seek a legislative proposal at this time but continue to believe that such a legislative change would significantly improve the Medicaid

drug rebate program. Over the last several years, our staffs have worked well together on Medicaid drug rebate issues. We look forward to that continued outstanding relationship and offer our assistance to HCFA as you contemplate changes to the Medicaid drug program.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-97-00052 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NEED TO ESTABLISH CONNECTION BETWEEN THE CALCULATION OF MEDICAID DRUG REBATES AND REIMBURSEMENT FOR MEDICAID DRUGS

JUNE GIBBS BROWN
Inspector General

MAY 1998
A-06-97-00052

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date MAY 8 1998

From June Gibbs Brown
Inspector General

Subject Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

An Anomaly: Medicaid drug purchases are made using average wholesale prices while drug rebates are made using average manufacturers prices

This final report provides you with our analysis of enhanced Medicaid revenues possible through use of the average wholesale price (AWP) in the calculation of Medicaid drug rebates. Since the inception of the Medicaid prescription drug rebate program which was created by the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the Office of Inspector General (OIG) has reviewed major aspects of the rebate program and recommended program improvements. The Health Care Financing Administration (HCFA) has been supportive of our efforts and has implemented many of our recommendations.

However, we believe that HCFA has an opportunity to address an issue which impacts the very core of the program--the disparity between how Medicaid drug rebates are based and calculated, and how the Medicaid program reimburses pharmacies for prescription drug purchases. We believe that the current program of basing rebates on a manufacturer calculated average manufacturers' price (AMP) should be changed to calculating rebates based on AWP.

Enactment of a legislative change requiring that rebates be based on AWPs would have resulted in about $1.15 billion in added Medicaid rebates for the Calendar Years (CY) 1994 through 1996 for only the 100 drugs used in our analysis.[1] Requiring manufacturers to pay Medicaid drug rebates based on AWP would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate AMP;
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid's reimbursement for drugs at the pharmacy level; and

[1]We studied the financial effects for the 100 brand name drugs comprising the highest total of Medicaid reimbursements in each of the CYs.

- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

We recommended that HCFA develop and submit a legislative proposal to the Congress that would require drug manufacturers participating in the Medicaid outpatient prescription drug program to pay Medicaid drug rebates based on AWP. We recognize that the opportunity exists that manufacturers could manipulate such a new system but believe that the normal competitive pressures on drug prices in the marketplace would discourage manufacturers from inordinately raising drug prices. However, we are also recommending that if our recommended change is enacted, HCFA should establish safeguards as part of the new rebate process to discourage manufacturers from inordinately raising drug prices to pay for the cost of the additional rebates and at the same time raising AWP to cover the amount of the increased cost to the pharmacies. One such safeguard would be for HCFA to complete an analysis of the historic AWP increases and seek authority to establish appropriate indexing methodology for use when AWP increases would exceed inflation.

We believe strongly that the Medicaid reimbursement and rebate methodologies for pharmaceutical transactions needs to be based on the same type of information. Therefore, if HCFA is not in agreement with supporting our recommended legislative proposal, then we are recommending that HCFA study alternative methods of calculating Medicaid drug rebates which would address our concerns with the current program.

In responding to our draft report, HCFA disagreed with our recommendations because they did not believe such legislation was feasible at this time. However, HCFA did agree that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. And, HCFA believes the calculation of AWP itself needs to be examined. The full text of the Administrator's comments is included as Appendix 2 to this report.

BACKGROUND

The OBRA 90 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. In order for a manufacturer's drugs to be eligible for reimbursement under Medicaid, the manufacturer was required by OBRA 90 to enter into a rebate agreement with HCFA and pay quarterly rebates to the States. The rebate is based on the AMP paid by wholesalers for drugs distributed to the retail pharmacy class of trade. Rebates are calculated by manufacturers separately for brand name drugs and generic drugs. For brand name drugs, the rebate amount is determined by taking the greater of either AMP minus the manufacturer's best price (lowest price) or a specified percentage, currently 15.1 percent of AMP. The rebate for generic drugs is calculated as 11 percent of AMP. There is an additional rebate amount for brand name drugs equal to the amount that AMP increases over and above the consumer price index. The AMP was indexed to the Consumer Price Index-Urban as of September 1990.

Contrary to how the above rebates are calculated, most States reimburse pharmacies for Medicaid prescription drugs based on the AWP of the drug. The AWP is the price assigned to the drug by its manufacturer and is listed in either the **Red Book, Medispan**, or the **Blue**

Book—publications nationally recognized for drug product and pricing information. Reimbursement is predominantly calculated as about 10 percent discount off the AWP.

Objective, Scope, and Methodology

The objective of this report was to provide HCFA with information on the impact of using AWP instead of AMP in the Medicaid drug rebate calculation. We developed this information by consolidating the results of our work performed at drug manufacturers and results from other audits of drug rebate issues. We also identified related benefits which could result from this proposal and calculated any additional rebates that could be realized by introducing a legislative change to modify the present drug rebate formula.

Our calculations of the increased rebates that could be realized by using AWP in place of AMP were for only the 100 brand name drugs which comprised the highest total amount of Medicaid reimbursements in each of the CYs 1994, 1995, and 1996. The estimate of rebate amounts using AWP was calculated by substituting AWP for AMP in the rebate formula and did not include the additional rebate calculations related to indexing. For each quarter's rebate calculation, we used the AWP that was in effect as of the end of that quarter. For the estimate of actual rebate amounts, we used the unit rebate amounts recorded in the HCFA Data Center, which included the additional rebate from indexing. Therefore, our estimated increase in the use of AWP is understated because we did not apply an indexing amount to our AWP based rebate calculation.

RESULTS OF REVIEW

Significant improvements to the Medicaid outpatient prescription drug rebate program are possible by having legislation enacted which would require participating drug manufacturers to pay Medicaid drug rebates based on AWP rather than AMP. Such a change would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate AMP;
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursements for drugs at the pharmacy level; and
- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

If this change is enacted, we believe that HCFA should establish safeguards as part of the new rebate process to discourage manufacturers from raising the prices they charge pharmacies to pay for the additional cost of the rebates while at the same time raising AWP to offset these price increases to the pharmacies. Such manipulation could result in an overall increase in the total cost of the Medicaid program. One such safeguard would be for HCFA to complete an analysis of the historic AWP increases and seek authority to establish an appropriate indexing methodology for use when AWP increases would exceed inflation. If HCFA is not in agreement with such a legislative proposal, then we believe that HCFA

should study alternative methods of calculating Medicaid drug rebates which would address our concerns with the current program. An alternative such as the calculation of the rebate based on the use of a flat percentage of drug manufacturers' sales would greatly simplify the program and address most of our concerns with the current program but also only if this methodology also included an excessive inflationary index calculation.

Inconsistent Methods Used by Drug Manufacturers to Calculate AMP

The AMPs submitted by drug manufacturers to HCFA provide the foundation upon which the entire Medicaid drug rebate program is based. However, we found that manufacturers have used inconsistent methods to calculate AMP because these manufacturers have interpreted the definition of AMP differently. In our first review of drug manufacturers involving four companies, we reported in 1992 that these companies used three different methods to calculate AMP because they lacked specific guidance on how to calculate AMP [Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program (A-06-91-00092)]. One of the manufacturers based the calculations on gross sales to its wholesalers, two of the manufacturers based the calculations on net sales to their wholesalers and another manufacturer specifically identified sales at the retail level for its calculations. As a result, we were unable to express an opinion on the accuracy of the AMP calculations at these manufacturers. The HCFA responded to our report and its recommendations by stating their intention to clarify the description of AMP in a future regulation. However, with input from the OIG, HCFA is continuing to revise final regulations for the drug rebate program. These revisions include changes to the definition of adequate documentation, retail class of trade, and AMP calculations.

In 1994, we reviewed another drug manufacturer's AMP calculations and we were again unable to express an opinion on the accuracy of the AMP calculations. This manufacturer used a methodology to compute AMP which it could not support. In that report, we also cautioned HCFA that manufacturers may submit revised AMP calculations and that such retroactive calculations could pose potentially significant liabilities to both the States and the Federal Government.

Subsequently, another drug manufacturer claimed that it had incorrectly calculated AMP and requested a multi-million dollar retroactive adjustment to its rebate payments. The HCFA approved the adjustment (subject to OIG audit) and allowed the manufacturer to offset the adjustment against current rebate payments to the States. The HCFA also allowed the manufacturer to use the revised methodology for its current and future AMP calculations, but requested that the OIG audit the manufacturer's calculations. We issued another disclaimer of opinion on the AMP calculations because of problems with the definition of AMP at this manufacturer.

We believe that as long as drug rebates are based on AMP as currently defined, HCFA will have continuing problems with manufacturers interpreting AMP differently due to differences in business philosophies, accounting systems, and market structure. We believe that as manufacturers find that AMP can be interpreted more to their benefit, additional requests for retroactive adjustments as well as changes in current and future calculations will

be forthcoming. This could significantly impact upon liabilities of the States and the Federal Government as well as impacting future Medicaid drug rebate revenue.

Connection Between How Rebates Are Paid and How Drugs Are Reimbursed

Under the present Medicaid prescription drug program, there is no direct financial connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursements to pharmacies for prescription drugs. As discussed above, drug manufacturers pay rebates by using AMP in the rebate formula. However, most States reimburse pharmacies based upon AWP less a discount of about 10 percent.

Because AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share. For example, by increasing AWP, manufacturers can give pharmacies more Medicaid reimbursement without having to make additional rebate payments. The drug industry currently treats AWP as a published list price rather than a true wholesale price.

Recently, we met with representatives from eight State Medicaid pharmacy programs to discuss our proposal to directly relate the calculation of rebates with the calculation of reimbursements. These officials were very supportive of our proposal and believed that such a change would make AWP a more meaningful and accurate number.

Reducing the Burden of Administering the Rebate Program

The creation of the new Medicaid rebate program with the passage of OBRA 90 placed a significant administrative burden on HCFA, the States, and the drug manufacturers. Requiring drug manufacturers to pay rebates based on AWP would reduce the administrative burden at HCFA and manufacturers. The HCFA would no longer have to collect AMP data from manufacturers but could use published AWP data. Drug manufacturers would no longer have to calculate AMP for a multitude of drug products by capturing data through accounting systems which were not originally designed for this purpose. Although drug manufacturers now have these systems in place, we believe that manufacturers would welcome being relieved from this burden.

By changing from AMP to AWP, manufacturers could easily manipulate, through changes to the published AWPs, how much rebates they pay. However, reductions in rebates due to reductions in the AWPs set by manufacturers would also result in a corresponding reduction in Medicaid pharmacy reimbursements. Another possibility would be unwarranted or unsupported increases in the AWP values. Manipulation of AWPs by raising them greater than the rise in rebate values would unfairly enrich manufacturers if manufacturers raised the prices they charge pharmacies. Therefore, including an indexing methodology in a revamped rebate calculation methodology that uses AWP as the base would be needed to discourage manufacturers from any pricing manipulations.

Calculation of Potential Increases in Rebates

We calculated that using AWP in place of AMP could have resulted in $1.15 billion more in drug rebates for 100 brand name drugs which had the greatest amount of Medicaid reimbursements in each CY of 1994 through 1996. The estimate of rebate amounts using AWP was calculated by substituting AWP for AMP in the rebate formula and did not include the additional rebate calculations related to indexing. Therefore, our savings calculation is understated.

For each quarter's rebate calculation, we used the AWP that was in effect as of the end of that quarter. For the estimate of actual rebate amounts, we used the unit rebate amounts recorded in the HCFA Data Center, which included the additional rebate from indexing. Although significant savings could be achieved upon passage of proposed legislative changes, HCFA could include a phase-in period to alleviate concerns regarding the adverse impact that may occur if a sudden change were made in the rebate program.

The following chart depicts the results of our calculations:

Calendar Year	Actual Rebates (millions)	Rebates Based on AWP (millions)	Increase in Rebates (millions)
1994	$685	$1,038	$353
1995	$726	$1,089	$363
1996	$735	$1,167	$432
Totals	$2,146	$3,294	$1,148

We recognize that there is the potential for manufacturers to manipulate the system if the basis for rebate calculations is changed from AMP to AWP. For example, manufacturers could significantly raise the prices they charge to pharmacies for drugs to cover the additional cost of rebates based upon AWP. The manufacturers could then offset this added cost to the pharmacies with even larger increases in the published AWP. This would result in a higher overall cost to the Medicaid program.

We believe that the normal competitive pressures on drug prices in the marketplace would discourage manufacturers from inordinately raising drug prices under such a scenario. However, we believe that HCFA should implement appropriate safeguards to preclude such manipulation if legislation is enacted to make AWP the basis for rebates. These safeguards could involve HCFA studying AWP increases and taking action to limit reimbursement when AWP increases exceed historic increases through the establishment of an appropriate indexing methodology. For the top 100 brand name drugs, the increases in AWP were 4.04 percent for the period January 1, 1994 to December 31, 1994, 3.71 percent for the period January 1, 1995 to December 31, 1995, and 3.91 percent for the period January 1, 1996 to December 31, 1996.

Other Alternatives

If HCFA is unwilling to support a legislative change, then we believe that HCFA should study other viable alternatives to the current program which would address the current problems with the use of AMP. For example, a greatly simplified rebate program which calculates rebates as a percentage of a manufacturer's gross sales would address definitional and documentation problems and administrative burdens associated with using AMP.

CONCLUSIONS AND RECOMMENDATIONS

While basing rebates on AMP is mandated by current legislation, we believe that a legislative change to have manufacturers pay rebates based on AWP would be a major improvement to the Medicaid drug rebate program. Such a change would resolve manufacturers' definitional problems with AMP, preclude the likelihood of future retroactive requests for rebate refunds and provide relief on the burden for administering the program. Significant cost savings could also be achieved. We also recognize that safeguards may need to be established to discourage manufacturers from inordinately raising prices to offset the cost of the additional rebates. Lastly, we recognize that there may be other alternatives that need further study. Therefore, we recommend that HCFA:

- Develop and submit a legislative proposal to the Congress which would require participating drug manufacturers to pay rebates based upon AWP. We are available to work with HCFA officials to develop specific language for the recommended proposal.

- If such a proposal is enacted, establish safeguards to ensure that manufacturers do not raise AWP to pay for the cost of the additional rebate collections by in turn raising the prices paid by pharmacies. The HCFA could study historic AWP increases and take action through the establishment of an appropriate indexing methodology if AWP increases exceed inflation.

- Study other viable alternatives to the current program of using AMP to calculate the Medicaid rebates. Alternatives such as the establishment of a flat percentage of manufacturers gross sales to calculate rebates could greatly simplify the program.

HCFA COMMENTS

In responding to our draft report, HCFA disagreed with our recommendation for development and submission of a legislative proposal to Congress on the issue. The HCFA does not believe that such legislation is feasible at this time. A statement was made by HCFA, however, that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. However, the response stated that the calculation of AWP itself needs to be examined, and HCFA is planning a comprehensive study of AWP.

We appreciate HCFA's position of not wanting to seek a legislative proposal at this time but continue to believe that such a legislative change would significantly improve the Medicaid drug rebate program. Over the last several years, our staffs have worked together on

Medicaid drug rebate issues. We look forward to that continued outstanding relationship and offer our assistance to HCFA as you contemplate changes to the Medicaid drug program.

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
1	$20,814,635.87	$19,419,447.19	$32,647,280.39
2	19,470,833.54	15,419,174.04	18,659,304.37
3	7,079,730.35	8,181,797.05	9,385,035.79
4	11,527,706.58	13,082,939.33	18,736,901.30
5	14,188,361.72	11,132,272.23	7,904,576.90
6	4,363,495.22	5,510,331.97	13,288,589.15
7	7,712,113.20	3,235,907.78	10,478,074.06
8	3,257,290.53	7,665,484.74	8,553,629.53
9	3,980,647.43	8,415,529.18	7,147,904.56
10	7,890,947.69	2,257,061.94	10,200,269.01
11	2,810,101.59	3,963,039.62	5,310,228.05
12	8,761,991.43	8,683,883.96	12,093.94
13	2,155,376.87	8,649,940.66	3,694,594.53
14	6,132,031.75	9,218,922.21	1,111,026.74
15	2,608,809.69	2,533,819.66	9,942,726.41
16	7,799,141.11	3,652,312.31	8,493,071.38
17	4,127,912.81	5,996,057.95	4,956,558.31
18	5,990,904.95	5,784,488.73	8,938,452.83
19	6,109,911.89	8,676,679.48	7,967,156.38
20	1,156,933.65	2,667,568.86	3,488,888.53
21	871,773.19	294,563.59	6,169,318.08
22	2,587,817.35	594,708.52	5,920,636.95
23	5,934,997.46	5,699,844.22	7,656,180.60
24	(2,714,778.07)	6,176,352.72	781,819.30
25	4,787,256.51	6,724,980.40	3,979,057.09
26	3,664,343.76	5,314,701.07	(378,649.79)
27	8,124,204.93	4,855,555.28	6,035,359.83
28	5,022,655.45	818,348.65	4,525,191.11
29	748,125.94	4,354,411.27	2,587,553.92
30	2,573,459.87	2,738,361.99	6,003,361.41
31	3,045,546.46	5,886,489.76	1,032,560.46
32	5,361,187.55	(3,775,723.48)	6,872,673.37
33	5,199,997.37	5,812,747.94	6,315,208.91
34	3,358,051.32	5,413,338.77	5,582,613.76
35	2,338,363.89	515,026.32	5,499,952.66
36	4,644,144.66	5,527,590.80	1,948,631.25
37	(1,745,834.47)	2,584,775.90	(4,100,614.44)
38	714,324.66	5,220,881.58	4,173,189.90
39	2,179,865.65	2,302,310.69	1,107,916.89
40	3,865,589.61	2,302,878.84	5,516,037.36
41	4,797,375.19	8,606,420.76	6,083,315.82

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
42	$4,327,565.29	$4,603,779.42	$2,606,060.63
43	2,147,258.84	(2,212,521.99)	4,280,576.55
44	3,539,643.42	4,055,078.49	3,002,570.51
45	4,507,067.92	(3,036,425.03)	(3,403,099.92)
46	3,263,240.78	6,086,840.03	3,615,586.16
47	6,036,152.57	2,915,417.22	(3,410,793.16)
48	1,506,711.09	2,287,283.67	8,361,659.41
49	2,062,237.58	2,024,531.91	2,724,437.39
50	(1,990,857.28)	1,585,704.17	5,151,002.91
51	11,799,114.32	2,308,609.91	4,857,157.56
52	1,950,395.54	4,560,678.22	3,707,669.09
53	1,157,707.31	3,368,704.11	5,217,609.64
54	3,289,421.36	1,122,929.75	4,511,092.05
55	981,388.28	3,898,876.10	2,921,132.87
56	1,159,718.05	1,142,813.12	2,483,790.54
57	2,178,707.39	3,017,728.38	3,051,875.82
58	4,242,308.60	2,222,057.33	4,712,723.81
59	2,804,611.06	10,769,548.93	3,573,468.64
60	1,541,888.09	2,031,624.94	4,341,222.52
61	3,208,855.58	3,686,358.95	4,564,079.60
62	3,689,427.23	3,904,601.87	3,363,671.81
63	1,319,367.69	1,724,497.06	3,900,717.51
64	2,595,961.23	2,556,148.32	2,826,120.77
65	3,130,260.76	611,001.35	3,276,100.70
66	1,789,009.52	3,324,130.78	1,105,618.80
67	2,602,436.67	3,747,927.32	3,025,129.80
68	1,248,499.77	2,694,068.24	3,470,780.23
69	1,360,049.60	1,439,813.22	4,431,607.85
70	4,642,037.38	2,460,769.07	1,215,971.77
71	2,448,505.29	1,615,017.85	3,419,302.28
72	822,758.90	1,387,916.54	647,920.86
73	2,262,192.07	2,388,826.88	2,367,857.90
74	792,409.01	1,213,809.77	1,026,315.83
75	2,861,027.55	3,193,552.05	1,635,254.62
76	4,861,186.41	2,896,174.54	13,186,929.69
77	3,276,246.50	2,661,067.79	658,404.85
78	6,271,455.43	3,251,271.30	7,300,295.66
79	2,780,890.23	3,171,767.40	2,742,464.48
80	(681,069.91)	2,578,987.65	1,541,450.70
81	884,742.47	849,595.72	729,384.43
82	1,144,404.23	970,198.20	3,576,216.40

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
83	$2,033,553.76	$861,562.52	$2,218,790.61
84	692,675.05	1,103,466.06	1,928,308.79
85	(986,743.49)	1,082,824.26	2,814,707.56
86	2,736,853.87	815,526.91	393,756.83
87	756,682.83	1,872,896.14	2,166,304.01
88	1,258,038.57	1,039,002.82	2,285,342.09
89	1,022,331.63	(1,401,409.31)	1,437,896.25
90	2,887,375.68	1,004,608.41	1,173,801.28
91	2,067,522.36	4,859,233.90	1,554,716.60
92	1,114,847.40	800,854.96	1,721,386.63
93	839,580.13	2,728,437.43	(765,102.78)
94	4,299,171.16	2,316,663.90	(2,203,738.05)
95	(551,930.64)	3,331,152.73	883,624.55
96	2,750,992.70	1,116,383.96	1,449,809.30
97	1,926,143.37	1,900,768.37	1,163,073.42
98	1,093,922.71	603,321.76	1,098,086.29
99	3,194,615.44	1,668,654.67	4,552,957.51
100	2,926,224.82	277,900.34	1,513,729.41
	$353,174,137.32	$363,177,834.86	$431,932,466.46

* Top 100 brand name drugs for each calendar year.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: APR 6 1998

IG ✓
EAIG
SAIG
PDIG ✓
DIG-AS ✓
DIG-EC
DIG-EI
DIG-OI
DIG-MP
AIG-LC
OGC/IG ✓
ExecSec
Date Sent 4-9

TO: June Gibbs Brown
Inspector General

FROM: for Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052)

We reviewed this draft report, and greatly appreciate OIG's efforts in evaluating the Medicaid drug rebate program. However, we do not agree with the report's specific recommendation that the Health Care Financing Administration (HCFA) propose legislation to require that Medicaid rebates be based on the average wholesale price (AWP).

We do not believe such legislation would be feasible at this time. Manufacturers already appear to be paying significantly more in rebates than was anticipated when the rebate program was initiated. This would make passage of any such legislation highly unlikely in the immediate future.

Based on recommendations in other OIG reports, we have provided manufacturers with clarification on the proper calculation of the average manufacturer price (AMP). Recalculations by manufacturers based on HCFA's guidance have resulted in retroactive adjustments.

We do agree that changing from AMP to AWP would reduce the administrative burden involved in the AMP recalculations. However, calculation of AWP itself needs to be examined. We are planning a thoughtful, comprehensive study of issues such as how AWP is defined; how to safeguard against manipulation of AWPs to maximize reimbursement or minimize rebates; how to verify the accuracy of AWPs; the need for an indexing factor; and differences in AWPs for brand name versus generic drugs.

We look forward to working with OIG in examining and refining the current AWP process so that it can benefit the Medicaid drug program.

EXHIBIT 4

MEDICAID DRUG REBATE DISPUTE RESOLUTION PROGRAM

I. HOW MANUFACTURERS CAN AVOID UNNECESSARY DISPUTES

1) The Manufacturer's Rebate Coordinator Should be Familiar With Various Aspects Of The Company's Product Line

Many disputes arise due to what appears to be excessive units dispensed per prescription of a National Drug Code (NDC) number. Although the units may appear to be inflated, there may be a reasonable explanation or circumstance to justify the "higher than normal" dispensing quantity. These types of disputes might be avoided if the manufacturer's rebate coordinator becomes familiar with several aspects of their company's product line. Key things that the coordinator should know are:

- *Condition/Illness For Which Product Is Indicated*

The product's indication will play an important role in determination of the expected usage of the product. For example, maintenance medications are usually dispensed in larger units per prescription than acute care medications. Additionally, certain diseases, such as AIDS or cancer, may require higher than average dosing or off-label usage of drugs, resulting in a larger number of units per prescription.

- *Correct Product Dosing*

Is the product prescribed twice daily or as needed? By knowing correct dosing, along with the expected duration of therapy, the coordinator can estimate an expected prescription size or typical number of units per prescription. This information may be helpful when trying to identify if an error in pharmacy billings has caused invoiced units to be overstated. As discussed above, certain indications or diseases may require dispensings for more than an average number of units per prescription.

- *Product Formulation*

It is important that the manufacturer's Medicaid drug rebate coordinator know the drug's formulation. Is the product a liquid or a gel capsule? Is the injectable product in solution or a powder-filled vial? The drug's formulation will determine the correct unit of measure for billing and invoicing. Knowledge of the drug's formulation will help the coordinator identify any potential errors in pharmacy billings caused by units billed in the wrong unit of measure.

- *Product Package Size*

The product's packaging size or packaging characteristics may affect the number of units typically dispensed per prescription. For example, a 20 gm tube of cream will have a dispensing quantity typically lower than the 60 gm tube of the same cream. Individual units of a drug packaged together in an unbreakable package may be reported as a kit, rather than as the sum of the individual units. A common error made by pharmacists when billing injectable powder-filled vials is to bill for the capacity of the vial to hold diluent (e.g., 10 ml) rather than to bill "each" for each vial dispensed. A good understanding of the product packaging may help to identify the potential for billing errors to occur.

- *Product Distribution Patterns*

Many manufacturer rebate coordinators review internal product sales reports to determine if a state's reported utilization of a product is consistent with the manufacturer's expected utilization in that state. If a manufacturer chooses to use these reports to make decisions on whether to dispute state utilization information,

the rebate coordinator should be familiar with all of the distribution patterns for their products and determine whether the sales reports are accurately capturing and reporting all state utilization. For example, mail-order pharmacy dispensing, nursing home dispensing, out-of-state wholesalers, group contract purchases, and pharmacies dispensing across state borders are all issues that need to be evaluated in internal reporting.

2) The Manufacturer's Drug Rebate Coordinator Should Ensure That Rebate Information Has Been Accurately Reported to CMS and To Independent Data Sources

There are sometimes instances in which a state may invoice a manufacturer for a product and the manufacturer withholds all or partial payment on the product, not because the manufacturer questions the accuracy of the pharmacy billings, but due to rebate amount per unit issues or product rebate eligibility concerns. By timely reporting to CMS and to independent data sources, manufacturers can help CMS and the states to obtain accurate information so that invoices are correct and so that states do not continue to pay pharmacies for products that are expired or not rebate eligible. Timely and accurate reporting will subsequently preclude related disputes.

Reporting to CMS
Once a manufacturer enters into the drug rebate program, the manufacturer is required to report basic information to CMS. The information provided to CMS is used to develop the Unit Rebate Amounts (URAs) which are sent to states that in turn use the data to prepare rebate invoices. The data reported to CMS from manufacturers must be accurate. Errors in reporting data can lead to errors in the URAs, which can lead to errors in state invoices. As a result, errors in state invoices can lead to unnecessary balances. The following provides the information that the manufacturer is required to report to CMS and the time line for reporting.

WITHIN 30 DAYS OF ENTERING INTO THE MEDICAID DRUG REBATE PROGRAM

- *Baseline Data*

Baseline data is required for ALL drug products that have an NDC. Baseline data provides a "profile" of each product. Baseline data forms the basis for CMS' data system, which is called the Medicaid Drug Rebate (MDR) System. Baseline data provides the information about a manufacturer's product that is needed in order to determine how a rebate should be calculated. Baseline data fields may be found in the Operational Training Guide, Section F.

WITHIN 30 DAYS AFTER THE END OF EACH CALENDAR QUARTER

- *Best Price (BP) and Average Manufacturers Price (AMP)*

Manufacturers are required to submit BP and AMP information to CMS within 30 days of the end of each quarter. There is a distinct difference between the calculations of BP and AMP. The following guidelines should be used in conjunction with official CMS instruction to determine the BP and AMP:

- Best Price (BP) - BP is the **LOWEST PRICE AT** WHICH A PRODUCT IS SOLD regardless of the package size. The BP IS NOT a weighted average (see AMP). ALL package sizes of a product must contain the same BP. BP is submitted for all drugs categorized as "S" (Single-Source) and "I" (Innovator) drugs, but **NOT** for "N" (Non-Innovator Multiple-Source) drugs.

- Average Manufacturers Price (AMP) - AMP is a per unit, per product code (NDC#3) **WEIGHTED AVERAGE** based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. ALL package sizes of the same product code must have the same AMP. AMP is required for EACH NDC.

Manufacturers should take measures to verify that this information is reported on time and in accordance with established CMS formats. Because CMS actually calculates the URA on each NDC from the submitted BP and AMP data from the manufacturer, rounding differences may sometimes occur between CMS' calculation and the manufacturer's calculation.

- *Drug- Category*

For purposes of the Drug Rebate Program, the Drug Category designates whether a drug is classified as a Single-Source (S), Innovator (I), or Non-Innovator Multiple-Source (N) drug. The Drug Category is one of the "Baseline" data fields. The drug category will determine the rebate percentage. Generally speaking, the S & I drugs are brand name drugs and the N drugs are generic drugs.

- *Date Product Entered Market*

The product market date, for purposes of Medicaid drug rebates, is defined as the date the product entered the market and was offered for sale. If marketed prior to 10-01-90, the date entered market would be the first day of the first month that the drug was mareketed for the entire month; othewise, it will be the actual date the product was marketed.
The rebate coordinator should be familiar with the market date for the manufacturer's product because it will affect the URA CMS calculates and sends to the states.

- *Correct Listing Of Unit Types/Units Per Package Size (UPPS)*

Manufacturers should review information from CMS, the Operational Training Guide, as well as other data sources such as the Red Book and First Data Bank, to ensure that UNIT TYPES and UPPS are listed correctly with all of these sources. Unit types and UPPS must be developed together. A unit type MUST BE designated as the SMALLEST identifiable amount for which a product can be sold. There are seven specific unit type values and "EA" (each) for some products (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, and grams for ointments). ALL PRICING IS **BASED ON THE UNIT TYPE**. If a unit type is "ML," then pricing reflects one ML for the product.

The value for the UPPS will vary depending on whether the product package can be broken and dispensed in smaller amounts. For example, if a product with a unit type of "CAP" (capsule) comes in a bottle with 100 capsules and can be dispensed in the amount of 10, 20, 30, etc., capsules, then the UPPS is "1." However, when a product **MUST BE** dispensed as it is packaged (cannot be broken into smaller units), the UPPS will be the actual size of the package. For example, a 12-pack of suppositories (which is the standard dosage for some products) must be dispensed as a 12-pack, then the UPPS is "12".

- *Follow Up To Ensure Corrections/Edits Are Made*

The use of outdated or otherwise incorrect pricing information by CMS when calculating rebate information will lead to incorrect calculations by states, and therefore create unnecessary balances. In order to avoid this, once a manufacturer is notified by CMS that its pricing data failed to pass edits, the manufacturer should

promptly contact CMS to resubmit correct data. The manufacturer should also inform any independent data sources, such as First Data Bank and the Red Book, of any changes, as these independent data sources also serve as information resources for states and pharmacy providers.

CMS processes the quarterly pricing data and sends edit reports to manufacturers. Edit reports are sent to the manufacturer when data submitted to CMS falls into an "alert" message or data is "rejected." Quarterly pricing data can be "rejected" for a number of reasons including:

- AMP/BP is not numeric
- AMP/BP is missing
- There is no Baseline record on CMS' MDR for the NDC

There are also several reasons the edit report will contain an "alert" message.

- BP is greater than the AMP
- DESI indicator change attempted

The manufacturer should make every effort to correct information on the edit reports and return the updated data to CMS before the MDR system is shutdown for rebate calculations (about 45 days after the end of the quarter). See Section G of the Operational Training Guide.

- *Termination Date/Expired Drugs*

The rebate coordinator should be aware of which drugs in the company's product line are no longer manufactured. There are a number of reasons a drug may no longer be manufactured, including: the drug being pulled from the shelf for health or safety reasons; the drug being replaced by an improved version; or the drug being discontinued due to low sales. In any case, the Termination Date must be reported to CMS. If the drug is pulled from the shelf for health or safety reasons, the Termination Date is the date removed from sale. However, if the drug is terminated for other reasons, the Termination Date is the shelf-life expiration date of the last batch sold.

Manufacturers are required to report pricing information for terminated or expired drugs for FOUR QUARTERS beyond the termination date. Manufacturers must pay rebates for discontinued products that still have effective shelf lives.

- *Selling of Product to Another Manufacturer (NDC)*

The manufacturer whose 5-digit labeler code (first five digits of the NDC numbre) appears on the product sold is responsible for paying rebates on that product. If the original manufacturer of the product sells the product to another manufacturer**/repackager/relabeler** and the original manufacturer's labeler code still appears on the product, the original manufacturer should forward rebate information to the new owner or make whatever arrangements necessary to assure that rebate payments are made timely. Since the original manufacturer is responsible for rebates on that product, the original manufacturer should verify that the new owner has properly paid the rebates due.

- *Changes in Manufacturer Contacts*

In addition to pricing data, manufacturers should notify CMS as soon as possible when a change occurs with respect to the contact person(s) and their correct address and information. This will avoid any potentially lost invoices due to states receiving and utilizing incorrect and/or outdated contact information from CMS. Updates on

manufacturer's contacts help assure that states send invoices to the appropriate person and assist in promoting better communication. Changes should be reported to CMS on form CMS-367a, found on page M4/5 of the Operational Training Guide, and faxed to (410) 786-0390.

- *Reporting Penalties and Suspension/Termination*

The manufacturer needs to be aware of the penalties involved in failing to report information to CMS and in reporting false information to CMS. The National Rebate Agreement and statute provides that a manufacturer may be assessed a civil monetary penalty of $10,000 for each day that the manufacturer fails to report AMP and BP or the list of covered outpatient drugs to CMS. In addition, a manufacturer that knowingly provides false information may be assessed a civil monetary penalty of $100,000. The same civil monetary penalty of $100,000 may be assessed if a manufacturer refuses to respond to a request for pricing information from CMS or provides false information. Additionally, CMS may pursue suspension or termination actions for good cause reasons.

Reporting to Independent Data Sources

Manufacturers are not required to report data to independent data sources. However, many state Medicaid programs and pharmacy providers utilize drug data from independent data sources such as MediSpan, First Data Bank, and Redbook. For this reason, manufacturers should provide basic product information for all NDCs (e.g., product description, product indication, AWP, unit type, package size, etc.) to independent data sources. In addition, manufacturers should provide updates on pricing information for all NDCs. The manufacturer should make sure that the unit type and UPPS provided to independent data sources is accurate. For example, if a manufacturer uses 30 ML rather than 28.7 ML = 1 oz. for a tube of ointment, the manufacturer should report this information to the independent data sources. If unit type and UPPS information is inaccurate, then the state invoice may be inaccurate, thus leading to a dispute.

3) The Manufacturer's Rebate Coordinator Should Have An Understanding Of State Reimbursement Processes

State Medicaid programs have some discretion in establishing reimbursement policies for services covered by the Medicaid Program including drugs. These reimbursement policies usually involve payment to pharmacies for drug cost based on a percentage of AWP. There are many variations of reimbursement, including direct pricing, estimated acquisition cost (EAC), State maximum allowable cost (MAC), Federal upper limit (FUL), usual and customary, etc. The manufacturer's rebate coordinator should be aware of the various reimbursement processes for the states. The coordinator should also be aware that many pharmacies may be able to purchase drugs at prices far below AWP by taking advantage of discounts for volume purchasing, early payment of invoices, etc. Some state may provide this information on their web page.

- *Medicaid Rate vs. Usual and Customary*

A number of Medicaid Programs have established definitions of usual and customary as a way to define pricing for drugs paid for by the Medicaid program. In general,

states establish "usual and customary" definitions to assure the Program is charged the lowest price for drugs. Usual and customary pricing usually reflects the pharmacy's everyday price charged for a drug product. This price may be lower than the Medicaid program's allowed amount if the pharmacy sells the product as "loss leader," for example, or if the pharmacy competitively prices the product.

- *Most Favored Nation Policies*

Some states invoke "most favored nation" status in order to receive the lowest prices from pharmacies that those pharmacies charge other payers. "Most Favored Nation" policies help ensure the lowest price for a drug product by providers is billed to the Medicaid Program. The state Medicaid program will often refuse to reimburse at the rate being offered by the Medicaid program if a lower price is being charged to other entities (e.g., HMOs, PCS, MediMet, etc.).

- *Federal Upper Limits*

In 1987, regulations limited the amount that Medicaid could reimburse for drugs with available generic drugs under the Federal Upper Limit (FUL) Program. These limits are intended to assure that the Federal government acts as a prudent buyer of drugs. The concept of the FUL program is to achieve savings by taking advantage of the current market prices.

Until the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the FUL could be established only if all versions of a drug product had been classified as therapeutically equivalent (A-rate) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers were listed in the current editions of published national compendia. OBRA '90 expanded that criteria and permitted the establishment of a FUL for a drug product if there are three (or more) versions of the product rated therapeutically equivalent (A-rated) regardless of the ratings of other versions (B-rated). and at least three suppliers are listed in the current editions of published national compendia.

The states inform their pharmacies of the FUL reimbursement limits as the maximum cost for which the pharmacists can be reimbursed for these products.
Note: At the current time, CMS publishes the FUL list on their web page.
http://www.cms.hhs.gov/medicaid/drugs/drug10.asp

- *State MAC Pricing*

Some states have implemented a State Maximum Allowable Cost (MAC) program in addition to the Federal Upper Limit (FUL) program. The prices that states set for drugs in a State MAC program represents the maxium cost which the pharmacists can be reimbursed for those selected drugs. The criteria for setting the State MAC prices vary from state to state. Some states provides information on their MAC programs on their web page.

- *Dispensing fees*

Pharmacies participating in the Medicaid program are allowed to charge Medicaid a "reasonable" dispensing fee per prescription dispensed. Each state Medicaid program has the discretion, with CMS approval, to determine what "reasonable" means for their individual programs. Thus, the dispensing fee allowed by state Medicaid programs will vary from state to state. The rebate coordinator should be aware that states usually pays pharmacies a dispensing fee per prescription filled, and should be familiar with each state's dispensing fee. This will assist the rebate coordinator in evaluating the state's reimbursement on a drug. Again, each state may vary with

regard to payment of dispensing fees, including dispensing fees on refill prescriptions, third-party prescriptions, or drugs priced at usual and customary rates.

- *Recipient Copayment/Deductible*

Some states may require Medicaid recipients to make a copayment or to meet a deductible in order to receive drugs through the program. Recipient copayments will reduce the reimbursed amount for drugs and should be considered when analyzing the invoice for dispute. The copayment or deductible required may vary from state to state.

- *State Prescription Limits/Regulations For Products*

Some drugs or drug categories are often regulated by state Medicaid program policy concerning the number of units that can be dispensed per month or per prescription. Some states establish prescription limits per month (e.g., 3 per month). Monthly prescription limits may increase the number of days' supply per prescription and can result in large quantities dispensed per prescription. For example, some states regulate the duration of acute care dosing of Histamine H_2 Antagonists. Other states may require that birth control pills be dispensed in a three-month supply per dispensing. The manufacturer's rebate coordinator should try to become aware of state policies on prescription limits that may explain why dispensing averages may appear different from other state averages.

- *Excluded Drug Categories*

Certain drug categories may be excluded from the Medicaid drug rebate program, and are therefore considered "non-rebatable." Such products include vaccines, products for weight control, hair growth, products for smoking cessation, fertility treatments, syringes, etc. In addition, potentially excluded are products that require monitoring services to be purchased exclusively from the manufacturer or designee. Permissible restrictions or exclusions are at the discretion of each state. This provision may be found in Section 1927 of the Social Security Act.

- *Third-Party Liability (TPL)*

In some cases, Medicaid recipients may have other insurance coverage in addition to Medicaid. In these instances, Medicaid is considered to be the payer of last resort. TPL will reduce the reimbursed amount and should be considered when analyzing the state reimbursement amount. As a reminder, if a state Medicaid agency paid **any** portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug.

- *State Generic Substitution Laws*

Many state Medicaid programs have laws governing generic substitution. The manufacturer's rebate coordinator should also be knowledgeable of state generic substitution laws.

4) The Manufacturer's Rebate Coordinator Should Become Familiar With Heavily Discounted Prices

Sometimes, manufacturers will enter into individual agreements with different pharmacy providers whereby the dispensing pharmacy will receive a purchasing discount(s) from the manufacturer. These discounts may explain how pharmacies can use branded products and accept a reimbursement lower than typical for the branded product. The rebate coordinator should be aware of which pharmacies have entered into such agreements by verifying internal discounts or contracts with pharmacies prior to disputing based on an analysis of the state's reimbursement.

5) The Manufacturer's Rebate Coordinator Should Reconcile Detailed State Utilization Data (Sud) From External Data Sources With The State Invoice To Make Sure They Correspond with Each Other

Manufacturers should compare detailed SUD, especially data obtained from external data sources, with the invoice information submitted by the state to ensure that they correspond. There are many reasons why detailed SUD, whether obtained from the state or from external data sources, may vary from the submitted invoice. One common reason that variances occur is that some prescriptions may not have been captured when generating the data or may have been erroneously included. For example, Public Health Service (PHS) billings excluded from invoices may not have been extracted when generating utilization data for a manufacturer or for external data sources. The manufacturer's rebate coordinator should have an understanding of why variances occur in order to avoid disputing units that were never invoiced. Examples of how variances may occur include:

- prescriptions not captured by third-party data, such as physician dispensings/prescriptions;
- units from compounded prescriptions originally billed under a "dummy" NDC;
- units from PHS prescriptions (in/out of data); and
- nursing home prescriptions (sometimes pulled from a different file).

6) Learn From Previous Resolutions

Manufacturers can proactively avoid disputes by identifying recurring disputes. The manufacturer should call the state and identify the recurring problem. The state can then work with providers to correct billing for the NDC and possibly perform upfront edits to resolve the problem before the invoice is sent to the manufacturer. For example, some states have point-of-sale (POS) systems that round units which may result in disputes. The manufacturer's rebate coordinator should be aware of which states have POS systems which may result in discrepancies in units reported due to rounding. The manufacturer should contact the state to try to rectify the problem instead of disputing the state invoices every quarter.

7) Work With States To Resolve Discrepancies Before They Become Disputes

States should submit invoices to manufacturers within **15 days** after receiving Unit Rebate Amount (URA) data on the quarterly tape from CMS. Upon receipt of the state invoice, the manufacturer should review the invoice for any discrepancies. Manufacturers are required to pay rebates to states for all rebate eligible NDCs invoiced, except those which are disputed. A manufacturer may also pay the full rebate amount invoiced and still dispute the amount they feel is incorrrect, indicating such on the Reconciliation of State Invoice (ROSI). Note: disputes can only be based on the number of units invoiced per NDC.

Manufacturers are required to respond to a state invoice, either by paying the invoice or withholding payment on units submitted by the state which the manufacturer feels are questionable. The undisputed amount of the rebate must be paid within 38 calendar days from the date the state utilization data was postmarked. Failure to pay for all invoiced units in the required time frame will result in the beginning of the dispute resolution process, and the potential accrual of interest liability.

Manufacturers are encouraged to attempt to reconcile issues with SUD within the 38 calendar day time period. The manufacturer may request claims detail information from the state in order to verify billing information or may request that the state research the NDC and issue a response to questions the manufacturer might have. This quick approach to resolving questions regarding state invoices may prevent the need for a dispute. Timely research will also make it easier for pharmacy providers to locate records to verify billing information.

8) Educate New Staff

It is essential that manufacturers make arrangements for the education of new staff to ensure a smooth transition when replacing its rebate coordinator. New staff should be familiar with the Medicaid program and drug rebate legislation. In addition, new staff should become familiar with the information provided on our web page, the *Medicaid Drug Rebate Program Operational Training Guide,* and the numerous Drug Manufacturer Releases from CMS. This also includes ensuring that new staff is familiar with internal company policies, such as supplemental rebates, contracting language, etc.

9) Maintain Documentation

Complete and accurate records of all invoices paid, contacts with states, etc., should be maintained. The lack of adequate and accurate documentation prolongs the process of rebate payment, as well as the dispute resolution process. The maintenance of complete files will also help prevent problems due to manufacturer staff turnover from affecting the timely payment of disputes or resolution of outstanding disputes.

THE PROCESS OF MEDICAID DRUG REBATE DISPUTE RESOLUTION: TOP TEN STEPS FOR MANUFACTURERS

1. SCHEDULE/PRIORITIZE/UNDERSTAND RESOURCES
2. EXAMINE INTERNAL RECORDS TO DETERMINE UNPAID REBATE OR DISPUTE BALANCES. SIMULTANEOUSLY REQUEST AND LOOK AT STATE RECORDS TO COMPARE STATE'S RECORDS OF PAYMENT, RECEIPTS, INVOICED AMOUNTS, ETC.
3. AGREE ON A PROCESS THAT LEADS TO RESOLUTION
4. RECONCILE DIFFERENCES DUE TO ACCOUNTING BOOKKEEPING ERRORS
5. RECONCILE UTILIZATION DATA DISPUTES
6. AGREE TO NECESSARY UNIT ADJUSTMENTS FROM UTILIZATION DISPUTE DISCUSSION AND DOCUMENT APPROPRIATELY
7. COMPARE "CORRECTED" UNITS AND RATES TO RECORDS AGAIN TO DETERMINE FINAL DOLLAR BALANCES DUE FOR RESOLUTION
8. COMPLETE RESOLUTION ACKNOWLEDGMENT (RESOLUTION LETTER)
9. ISSUE RESOLUTION PAYMENTS AND INTEREST WITHIN A REASONABLE TIME PERIOD

10. POST RESOLUTION PAYMENTS AND DOCUMENT RESOLUTION CLOSURE

II. BEST PRACTICES IN MEDICAID DRUG REBATE DISPUTE RESOLUTION FOR MANUFACTURERS

The following discusses the Best Practices for Manufacturers in the Medicaid Dispute Resolution process. The Dispute Resolution process begins when the manufacturer notifies the state of a unit dispute. The dispute ends when the manufacturer and state reach resolution on all disputed units.

Each dispute may be unique, however, the process of Dispute Resolution should adhere to the following guidelines.

1) Schedule/Prioritiz/Understand Resources Available

Manufacturers should work with states to identify common priorities in order to resolve disputes. Aged disputes and those involving large dollar amounts should receive priority when both parties are attempting to decide when to begin working on resolving their disputes. In addition, as manufacturers attempt to get all balances to zero, they should target those states who are most capable and willing to participate first, as those disputes may be easily resolved.

Both parties must understand the resource capabilities of each side and understand the limitations. The manufacturer needs to consider its own staffing resources, as well as the staffing resources of the state. This directly ties into scheduling, because most scheduling occurs with the understanding of each party's capabilities. For example, a state may be working on end of fiscal year requirements and may therefore not have the resources to devote to resolving disputes with a particular manufacturer at that time. In instances where resources, especially staff and time, are an issue, both parties can reach an agreement to begin resolving their disputes at a later time. That time should be specified, however, as the goal should be to resolve disputes as soon as possible.

Another important resource issue for manufacturers to keep in mind is the technological capabilities of the states with whom they are attempting to resolve disputes. States with automated systems may have the capability to generate the information necessary to resolve disputes more quickly than a state with a manual system for information retrieval. In these instances, manufacturers may wish to consider attempting to work with those states who have more electronic capabilities first, allotting more time for those states whose systems' capabilities may not be as advanced.

Manufacturers should seek CMS Regional Office DRP Coordinator assistance with states that remain uncooperative after attempts have been made to initiate the dispute resolution process.
Note: The names of CMS DRP RO Coordinators may be found on the DRP web page.
http://www.cms.hhs.gov/medicaid/drugs/drp/drpcoor.pdf

2) Examine Internal Records To Determine Unpaid Rebate Or Dispute Balances. Simultaneously Request And Examine State Records To Compare Data

In order to begin dispute resolution efforts, the manufacturer should examine internal records to determine, by NDC, the number of any unpaid units and unpaid dollar amounts owed to the state. At the same time, the manufacturer should request a copy of state records to compare the manufacturer's accounting of balances outstanding with the state's assessment of amounts due. This comparison may assist in prioritizing and scheduling work efforts and exchange of information during the dispute process.

3) Agree On A Process That Leads To Resolution

Communication between the state and the manufacturer is a key element in the successful resolution of disputes. The initial phase of dispute resolution involves the exchange of information between the state and the manufacturer and informal negotiations and an assignment of duties between both parties. The manufacturer and state should agree on an approach that would best produce a resolution to the dispute.

4) Reconcile Differences Due To Bookkeeping/Accounting Errors

Due to the tremendous volume of financial postings involved with invoicing and the recording of manufacturer payments, both states and manufacturers may show outstanding rebate balances because of bookkeeping and accounting errors, rather than actual disputed issues. These balances are usually a result of discrepancies in the posting of rebate payments or a result of discrepancies in unit rebate amount.

Account Related Differences Due to Payment Receipt and Posting Discrepancies

Manufacturers should strive to compare state and manufacturer records to ascertain that payments and invoice details are identically recorded. Discrepancies should be jointly researched and resolved with state assistance. Manufacturers should be willing to assist states with proper allocation of payments, especially for payments made prior to the use of Reconciliation of State Invoice (ROSI) vouchers when payments may not have been clearly documented.

Manufacturers should verify that manufacturer-calculated rates match rates calculated and reported by CMS. Likewise, state reported rates should match those reported by both manufacturers and CMS. Control procedures should, at a minimum, include six-digit comparisons with CMS quarterly reports and with state's quarterly invoices. Discrepancies should be promptly researched and resubmitted to CMS, through prior period adjustment (PPA) reporting procedures (using the Prior Quarter Adjustment Statement (PQAS)), when appropriate.

Differences reported on state invoices should be pursued with the states. The resolution process should not be delayed while rate discrepancies are being researched. Parties are encouraged to expedite dispute resolution using manufacturer rates.

Some of the most common examples are:

Error. Misapplied payments
Solution: Supply payment voucher detailing application

Error. Duplicate payments

Solution: Supply check copies

Error. Missing rate adjustment
Solution: Supply rate information

Error. Rounding differences (state calculated vs. manufacturer calculated rebate amounts due)
Solution: Agree to resolve rounding differences
Error. Products sold to other manufacturers, but invoiced under original owner's labeler code
Solution: Invoiced manufacturer provides invoice information to new product owner for payment of rebates. Assure that new owner clearly indicates on payment voucher the invoiced NDC being rebated.
NOTE: The manufacturer whose labeler code appears on the product sold is responsible for paying rebates on that product.

Error. Miskeying of invoice information by manufacturer
Solution: Correct any miskeying errors

Error. Invoices not received by manufacturer
Solution: Obtain and pay missing invoices (including interest, if applicable)

5) Reconcile Unit Disputes

Disputes occur when a manufacturer questions the correctness of invoiced units. Such disputes can include units for which payment is withheld at the time the original invoice is paid, and units originally paid but later (retrospectively) questioned based on new information (e.g., detailed data, etc.). A manufacturer can only withhold payment for disputed units and must pay rebates (plus any applicable interest) for all undisputed units.

There are many reasons why manufacturers might question utilization information reported on state invoices. Some of the most common reasons for utilization disputes are listed below.

Problem: Unit Types (must be the smallest identifiable amount). Unit type reported in invoiced units does not match unit type of rebate amount per unit.

Problem. Units dispensed do not correlate with the Medicaid reimbursed amount.

Problem. Keying errors

Problem. Processing problems (Field justification problems, inappropriate conversions, etc.)

Problem. Rounding problems/incorrect decimal position

Problem. PHS billings

Problem. Terminated/expired drugs

Problem. Units billed under wrong NDC

Problem. Products sold to other manufacturers

Problem. Non-covered drugs/devices/services

BEST PRACTICES IN MEDICAID DRUG REBATE DISPUTE RESOLUTION FOR MANUFACTURERS

Before initiating a dispute, a manufacturer should consider the cost effectiveness of the dispute. The manufacturer may decide to pay the disputed invoice if it is not deemed cost-effective to pursue dispute resolution efforts. If not, the dispute resolution process continues.

Once the manufacturer decides to pursue a disputed issue, the manufacturer must provide the state with a detailed reason for the dispute so that the state can research the issue appropriately. (The Reconciliation of State Invoice (ROSI) is mandated for use by manufacturers to uniformly explain the adjusted rebate payments to state and allows for choosing codes to explain for adjustments and disputes per NDC.) If the manufacturer has claim detail utilization data available, the manufacturer should provide the state with a list of claims/providers in question for each disputed NDC in order to expedite research efforts for the state. Manufacturers should take time to validate claim detail information they have available to make sure that the number of claims and number of units in the detail data match invoice totals. Oftentimes, claim details obtained from the state or from third-party vendors contain claims, such as PHS billings, which were extracted during invoice generation and thus were not included in invoice totals. In other cases, claims invoiced may not be included in data obtained by third-party vendors. This is often the case with adjusted claims, physician dispensings, compounded prescriptions, and, on occasion, nursing home claims. Manufacturers need to know the validity of claim detail information as it relates to invoice information before using the data to analyze dispute issues. Manufacturers should provide last lot expiration dates to the states for all NDCs invoiced which are no longer rebate eligible.

After the state receives the ROSI and/or the PQAS, the state and manufacturer should discuss, by NDC number, the items disputed and the reason for dispute. The state should contact the manufacturer in writing or by telephone to discuss, by NDC number, the dispute, the reason for dispute and should present a report to the manufacturer of preliminary response to the dispute resolution. If the dispute is resolved, the manufacturer and state must both maintain supporting documentation of the resolution.

If the dispute is not resolved, the manufacturer should reach an agreement with the state as to a reasonable timeframe for the state to conduct the research necessary to provide requested information to the manufacturer. If the state makes a request for further information from the manufacturer, the manufacturer should honor that request as soon as possible so that the process will not be hampered.

The manufacturer may request additional documentation from the state to support invoiced utilization data. Additional documentation may include:

- Drug utilization data
- Zip-code level utilization data
- Pharmacy level utilization data
- Sampling of pharmacy claims

- Historical claims data

The state should attempt to resolve questions concerning data by reporting the findings of state research or by providing the documentation requested by the manufacturer. The type of data provided by the state must match the type of data requested by the manufacturer. Once the manufacturer has received the requested research from the state, the manufacturer should evaluate the information and determine if the dispute can be resolved.

If a manufacturer's concern involves a large number of claims for a given NDC, the state may perform a random sample of pharmacies to expedite time and research efforts. The sample size needs to be mutually agreeable to both the state and manufacturer.

Once the manufacturer is satisfied with the state's response to disputed issues, the resolution, in terms of corrected units, should be documented and made part of the drug rebate file.

6) Agree To Necessary Unit Adjustments From Utilization Dispute Discussion and Document Appropritely

Manufacturers and states should come to an agreement that is mutually acceptable to both parties based on data acceptable by both parties. A resolution can be made when state utilization data are corrected, when there is agreement that invoiced units are correct, OR both parties agree to a resolution based on mutually acceptable data that is more representative of actual Medicaid utilizaton. Any resolution reached should be appropriately documented, listing action steps taken by each party, results of all research conducted, unit changes made, and any follow up which is anticipated. A copy of resolution documentation should be kept in the manufacturer's files, as well as the state's files.

7) Compare "Corrected" Units and Rates to Records Again To Determine Final Dollar Blanaces Due For Resolution

Once the manufacturer and the state have reached an agreement regarding units and rates, and made any mutually agreed upon changes to their respective records, both parties should compare records once again to make sure that they agree as to the final dollar amounts required to bring balances to zero. Interest payments, if applicable, should be discussed and ageed upon.

8) Obtain Reconciliation Statement From State

Once the manufacturer and state have reached a point where their records correspond with the corrections that were mutually agreed to, the manufacturer should obtain a reconciliation statement/letter from the state. The statement/letter should reiterate the state's agreement that the balances specified in the statement accurately reflect the amounts needed to satisfy all unit issues. The statement should also specify the expectation of interest payment on balances due the state, if applicable. The appropriate state representative should sign the letter and a copy should be placed in the manufacturer's files.

9) Issue Resolution Payments And Interest Within A Reasonable Time Period

Upon receipt of the reconciliation statement/letter from the state, the manufacturer should issue a resolution payment, including any applicable interest, promptly within a reasonable time period. If the manufacturer is not able to include interest in the payment sent to the state, it should include a letter with the payment stating that the accumulated interest will be calculated and paid upon receipt of the state's signed agreement to the resolution. The manufacturer is responsible for calculating interest due to states on unpaid or late rebate payments. Payment of interest is not optional.

It is important to remember that a resolution may not only result in a manufacturer payment to the state, but may also result in a credit or reimbursement payment from the state, including any applicable interest. A credit due to a manufacturer as a result of dispute resolution findings may be taken against payment of a future invoice. Proper documentation of this application should be provided to the state for accurate posting.

10) Post Resolution Payments and Document Closure

Once the manufacturer has issued a resolution payment, including interest, to the state, or received a credit from the state, both parties should continue to work to post balances to zero. This may include ongoing discussions and the sharing of supporting documentation to ensure that both parties have all necessary information to post a zero balance. Once both parties have reached agreement and are able to post a zero balance, that agreement should be documented and maintained in both entities' files.

III. WHAT SHOULD MANUFACTURERS DO IF THE PROCESS FAILS?

1) Attempt To Go Through The Dispute Resolution Process/Encourage Other Party To Attend DRP Meeting

If repeated attempts to work with a state to resolve disputes remain unsuccessful, the manufacturer may want to consider encouraging the state to attend one of the DRP meetings. These meetings provide a setting in which states and manufacturers can often meet with several other parties during the course of the week, thereby providing a venue for resolving multiple disputes in a short period of time. In addition, CMS staff is present at the meetings and can serve as facilitators in the event that some difficult or seemingly unresolvable issues arise.
Our web page provides information and schedule for the National DRP Meetings:
http://www.cms.hhs.gov/medicaid/drugs/drp/default.asp

In addition, if the Drug Rebate Dispute Resolution Process for manufacturers fail, the manufacturer may require a state to schedule a hearing at any stage of the process if the state does not take the required actions of the dispute resolution process. Options other than a state hearing include:

- Mediation Review
- Non-Binding Arbitration
- Binding Arbitration
- Administrative Hearing

2) Contact CMS Regional Office To Try To Get The Other Party Engaged And To Encourage Them To Attend A DRP Meeting

If a manufacturer finds that after repeated attempts to resolve a dispute with a state remain unsuccessful, it may be necessary for the manufacturer to contact the appropriate CMS RO DRP Coordinators and request their intervention. The CMS RO can assist a manufacturer in persuading a state to begin the resolution process with the manufactureror.
The RO DRP Coordinator will keep Central Office (CO) informed of dispute issues.

Prior to contacting the RO, the manufacturer should make sure to differentiate between states that are unable to participate and those that are simply unwilling to do so. The manufacturer may want to consider arranging with a state that is unable to participate at that time (due to, for example, staffing or resource issues) to work on resolving their dispute at a later date. The state may simply be attempting to resolve aged or large dollar disputes with other manufacturers and may not currently have the resources to address the manufacturer's dispute at that time.

For states that are simply unwilling to enter into dispute resolution discussions, the intervention of the CMS RO DRP Coordinator may provide some assistance in getting that state to the discussion table.
Note: The names of CMS DRP RO Coordinators may be found on the DRP web page.
http://www.cms.hhs.gov/medicaid/drugs/drp/drpcoor.pdf

3) If Necessary, Contact CMS

If a manufacturer has exhausted all other options, including trying to reach an agreementwith a state to begin resolving the dispute at a later date and involving the CMS RO representative, and has not yet been able to engage the state in dispute resolution discussions, it may be necessary to seek the intervention of the CMS CO DRP Team. They will work closely with the DRP RO Coordinators in an effort to assist.

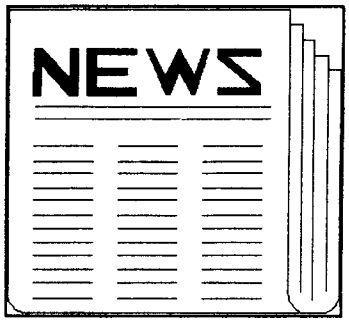
EXHIBIT 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207 – 5187

OCT 5 1995



MEDICAID DRUG REBATE PROGRAM Release No. 19

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

DISPUTE RESOLUTION ISSUES

We would like to take this opportunity to address several issues of concern regarding dispute resolution. We are providing this information to all States and manufacturers.

We have consistently maintained that disputes must be based on utilization data, which is consistent with the terms of the rebate agreement. While we recognize that manufacturers often review Medicaid reimbursement amounts for individual drugs to determine if the respective rebate amounts are appropriate, only units are subject to dispute. Further, the statute and rebate agreement clearly specify the formula for calculating rebates. The rebate calculation is that specified in the statute and rebate agreement irrespective of Medicaid reimbursement costs. It is a violation of the rebate agreement and the statute for a manufacturer to calculate rebates on any alternative formula other than that required by law and the rebate agreement. Consequently, the only basis upon which a manufacturer may dispute rebates is on utilization data and not on unit rebate amounts or Medicaid reimbursement.

It has been brought to our attention that some manufacturers have proposed settlements on disputed rebate amounts to States based solely on a dollar amount or a percentage of the disputed amount and have cited HCFA endorsement of their proposals. Such proposals for settlements on any basis other than units are unacceptable as we do not endorse any settlement which is not based on utilization changes. States and manufacturers assume the risks of audits and potential Federal recoupment actions by settling disputes on any basis other than units.

TERMINATION FROM THE REBATE PROGRAM

We have been notified by drug labelers that selected States are advising drug labelers that the States may terminate them from the Medicaid drug rebate program. Such threats are typically in response to a labeler's persistent reluctance to pay rebates to the State. A State does not have the authority to terminate a labeler from the national Medicaid drug rebate agreement and we have requested States to cease such notifications. Rather, we suggest that the State advise its respective regional office drug rebate coordinator if a labeler does not pay rebates. By law, the Secretary of DHHS retains the authority (which is delegated to the Medicaid Bureau within HCFA) to determine when termination action is necessary.

PRIOR AUTHORIZATION

Several drug labelers have reported States which place the entire drug formulary of a labeler on prior authorization, citing non-payment of rebates as the justification. Again, if a manufacturer refuses to pay rebates, the regional office should be notified. However, any State has the authority to place any drugs it chooses on prior authorization, provided the statutory requirements of a 24-hour response and 72-hour emergency supply are met.

PARTIAL DRUG REBATE PAYMENTS

We have received reports of States receiving partial payments of rebate amounts from labelers with a letter specifying that unless the State advises the labeler within a specified number of days to the contrary, the labeler will consider the partial payment as being payment in full and the dispute resolved. We do not consider a dispute to be settled until both the State and the labeler agree that it is settled and documented.

When a labeler submits a partial payment, the labeler must identify the unpaid units and amounts by National Drug Code.

The items described in this release are not intended to be all-inclusive of the problems inherent in the dispute resolution process and we intend to provide additional guidance in future letters. Meanwhile, we would like to reiterate that labelers and States are encouraged to resolve disputes in good faith and in a timely manner. We have significantly increased our focus in dispute resolution and, through our regional offices, we will enhance our efforts to more closely monitor the progress of States and labelers in resolving disputes.

If a State or manufacturer need additional assistance in dispute resolution after notifying the appropriate HCFA regional office drug rebate coordinator, please contact Mike Keogh, Medicaid Bureau Drug Rebate Team, at (410) 786-5910.

PUBLICATION OF DRUG REBATE REGULATIONS MB-46-P

The Medicaid drug rebate regulation, MB-46-P, was published in the Federal Register on September 19, 1995, 60 FR 48442-48490. The proposed rule specifies requirements for State Medicaid agencies and conditions under which Federal payments will be made under Medicaid for covered outpatient prescription drugs.

The 60-day comment period on the rule ends November 20, 1995. All written comments will be considered in the final rule.

Copies of the proposed rule are available through the following sources:

1. Federal Register.--To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

2. Internet.--HCFA's World Wide Web Home Page on the internet contains HCFA's regulations. HCFA's web site address is:

http://www.ssa.gov/hcfa/hcfahp2.html

3. CD-ROM.--HCFA's laws, regulations, and manuals are also available on CD-ROM. HCFA's latest update to CD-ROM included the Medicaid drug rebate regulation, MB-46-P. Interested parties can order this information from the following source:

Government Printing Office
Sales Order and Information Desk
(202) 512-1800

HCFA's Laws, Regulations and Manuals on CD-ROM
Stock Number: 717-139-00000-3
Price: $30.00 for each edition, $246.00 per year

Questions in this area should be referred to Estelle Chisholm at (410) 786-3286.

PRIOR PERIOD ADJUSTMENT (PPA) PROCESSING

In release #18, dated August 16, 1995, we covered the processing of PPAs and how they were to be initiated by the labelers to the States with subsequent follow-up to HCFA for verification.

Please remember that PPAs for **DRUG CATEGORIES** **"S"** and **"I"** will result whenever **BASELINE AMP** and/or **MARKET DATE** changes occur. When this happens, you are responsible for recalculating Unit Rebate Amounts (URAs) for any and all affected quarters (potentially back as far as calendar quarter 1-91) and for showing the differences to each State during the next billing cycle.

Additionally, baseline changes for Baseline AMP and Market Date made for products having multiple package sizes **MUST** have the same change made (and reflect all URA changes) to **ALL** package sizes. Any change that will cause URAs to be recalculated **MUST** be done by you and reported to HCFA and States in the very next reporting period.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1995 through October 2, 1995.

TOPIC INDEX

For your convenience, attached is a topic index of all items covered in prior releases.

Please remember to direct your drug rebate questions to a staff member on the listing we provided with release number 18.

Sally K. Richardson
Director
Medicaid Bureau

2 Attachments

cc:
All Regional Administrators
All Associate Regional Administrators Division of Medicaid

WEEKLY U.S. T-BILL DISCOUNT RATE

The latest weekly 90-day treasury bill auction rates for January 3, 1995 through October 2, 1995 are:

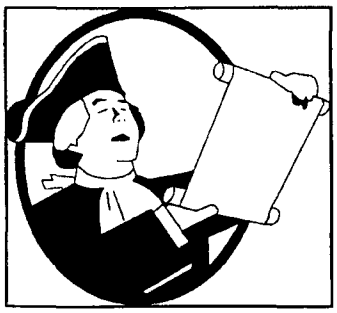
DATE OF AUCTION	TRUE DISCOUNT RATE
01/03/95	5.947
01/09/95	6.042
01/17/95	5.939
01/23/95	5.968
01/30/95	5.959
02/06/95	6.001
02/13/95	5.988
02/21/95	5.906
02/27/95	5.909
03/06/95	5.955
03/13/95	5.943
03/20/95	5.943
03/27/95	5.818
04/03/95	5.943
04/10/95	5.880
04/17/95	5.731
04/24/95	5.839
05/01/95	5.922
05/08/95	5.806
05/15/95	5.889
05/22/95	5.901
05/30/95	5.818
06/05/95	5.649
06/12/95	5.744
06/19/95	5.628
06/26/95	5.512
07/03/95	5.702
07/10/95	5.566
07/17/95	5.628
07/24/95	5.640
07/31/95	5.607
08/07/95	5.578
08/14/95	5.587
08/21/95	5.600
08/28/95	5.504
09/05/95	5.463
09/12/95	5.504
09/19/95	5.409
09/25/95	5.293
10/02/95	5.504

TOPICAL INDEX – DRUG MANUFACTURER RELEASES 1 – 19

TOPIC	RELEASE #
New Diskette Program/Data File	5
Omnibus Budget Reconciliation Act of 1993	9
Parenteral/Enteral Products	2
Partial Drug Rebate Payments	19
Powder–Filled Vials, Ampules, & Syringes	11
Prior Authorization	19
Prior Period Adjustment Processing	19
Proposed Discount Equal Access Legislation	16
Publication of Drug Rebate Regulations MB–46–P	19
Public Health Service Drug Pricing Program	13
Quarterly Pricing Data	3 – 8
Rebate Percentages for 1994	12
Rebates on OTC Drug Products	6
Remittance Advice Report (RAR)	7 – 15 – 16
Remittance Advice Report Implementation Workgroup	17 – 18
Reporting NDCs for Generic Products	4
Reporting Requirements	2 – 12
Separate Rebate Agreements with States	11
Shelf Life	3
Staff Relocation	16
State	
Hearing Process	13
Rebate Payments	3
Remittance Advice Contacts	9
State/Regional Office Drug Rebate Contact Persons	6 – 8 – 17
Termination From Program	19
Termination Appeal Process	11
Tolerance Threshold for Interest	15
Training Guide	18
Unique Medicaid Factors & Rebate Disputes	14
Unit–Dose Packaging	4
Unit Rebate Calculation (URA)	
Modification	2
New HCFA Edits	13
Unit Type	
Changes to Each (EA)	13
Conversion Date Change	9
Specification Changes	6 – 8
VA Appropiations Act	3
Veterans Health Care Act of 1992 (VHCA)	6
Virus Transmissio⁻ Via Diskette	16 – 18

(Revised 4 October 1995)

EXHIBIT 6



MEDICAID DRUG REBATE PROGRAM

Release Number 71

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All State Medicaid Directors

MISCELLANEOUS ITEMS REGARDING DISPUTE RESOLUTION ISSUES

At the request of numerous pharmaceutical and state representatives participating in our Dispute Resolution Project (DRP) and various drug rebate conferences, we are taking this opportunity to provide guidance on a few recurring items and issues related to drug rebate disputes. This guidance is not intended as all inclusive nor does it attempt to address all situations. Rather, our intention is to publish a "Best Practices Guide for Dispute Resolution Under the Medicaid Drug Rebate Program" later in 1998 in which we will include more comprehensive information for all states, pharmaceutical manufacturers and regional offices. At this time, however, we believe it is appropriate to provide some samples of situations encountered through the DRP. We are including this information in both the current state and manufacturer releases.

o Interest

Interest accrues on any and all rebate amounts not paid timely. Interest is not applicable to rebate payments due to recalculated URAs (prior period adjustments) or rebate payments made timely on utilization changes unrelated to disputes.

Example 1: Manufacturer A is invoiced for 1,000 units by State B. Manufacturer A pays rebates timely for 600 units, withholds payment on 400 units pending dispute resolution. Subsequently,

(after the 38-calendar day time frame to pay rebates timely) Manufacturer A agrees that 300 units of the unpaid 400 units should be paid, State B agrees to reduce the utilization by the remaining 100 units.

Manufacturer A asserts that interest is not due on the 300 units because it's a utilization change.

Answer: INCORRECT! Since the Manufacturer A did not timely pay rebates on the 300 units originally invoiced and subsequently agreed to do so, interest is due on those 300 units.

Example 2: Same scenario as Example 1, except that Manufacturer A paid rebates timely on the full 1,000 units then subsequently disputed 400 units. As a result of dispute resolution, State B agrees to reduce the utilization by 100 units.

Manufacturer A asserts that it is due credit for 100 units, plus interest on the 100 units reduced but paid timely.

Answer: CORRECT! Since Manufacturer A paid rebates timely on 1,000 units but subsequent dispute resolution agreement resulted in a reduction of 100 units, credit for 100 units plus interest is due to Manufacturer A. However, there is no interest due if the state agrees to credit the manufacturer for the 100 units within 38 calendar days of notification of the dispute.

Example 3: State C invoices Manufacturer D for 1,500 units and Manufacturer D timely pays rebates in full. Subsequently, State C discovers an additional 500 units that should have been included with that quarter's invoice.

State C asserts interest is due on the additional 500 units retroactive to the rebate due date of the first invoice.

Answer: INCORRECT! The additional 500 units are an initial utilization adjustment and interest is not due in this situation unless Manufacturer D subsequently fails to pay the additional rebates on the 500 units timely, then this situation is treated the same as an initial rebate dispute.

Example 4: Manufacturer E submits a unit rebate adjustment which results ultimately in a reduction of rebates already paid. Manufacturer E reduces current rebate payments by taking a credit for the previously overpaid amount plus interest.

Answer: This situation should be handled as follows: Manufacturer E should first notify HCFA of the unit rebate amount change. After HCFA approval, Manufacturer E should

make the necessary adjustments on the current quarters invoice and provide documentation of the adjustment/credit to the state. However, interest is never due on unit rebate adjustments.

Example 5: Manufacturer F timely paid rebates in full in the amount of $86,000 for State G for 1Q94. During dispute resolution meetings in 1996, it is initially discovered that due to an accounting and disbursement problem within Manufacturer F, a duplicate check for $86,000 was simultaneously issued with the original check to State G.

Manufacturer F asserts that a credit of $86,000 plus interest accruing from 1Q94 is due.

Answer: Clearly, a credit of $86,000 is due. But, based on these facts, we do not believe that interest is due.

Example 6: State H invoices Manufacturer I for 700 units; Manufacturer I pays nothing and disputes the entire 700 units. As a result of dispute resolution, State H agrees to reduce units by 600, leaving rebates for 100 units due.

Manufacturer I asserts that no interest is due since the state adjusted units.

Answer: INCORRECT! The unit adjustment was based on dispute resolution for rebates not paid timely by Manufacturer I. Interest is due on the 100 units, accruing from the rebate due date of the original invoice. Please refer to Example 3 for a situation where interest is not due on a unit adjustment.

Example 7: State J invoices Manufacturer K for 30,000 units; Manufacturer K pays nothing and does not notify State J of its intent to dispute. On the 50th day after Manufacturer K received the invoice, the manufacturer pays rebates on 10,000 units, without interest.

Answer: In this situation, Manufacture K failed to pay timely on any portion of the rebate amount. Interest is due on the 10,000 units, calculated from the rebate due date of the original invoice. Additionally, assuming that the state does not reduce its utilization, interest continues to accrue from the rebate due date of the original invoice on the remaining 20,000 units until the dispute is resolved.

Please refer to Section I of the Medicaid Drug Rebate Operational Training Guide for interest calculations.

If you have any general questions on interest, please contact Sue Gaston at (410) 786-6918.

o Thresholds/Tolerance Levels

It has come to our attention that there are still instances of states invoicing for rebates or interest in amounts as low as or less than $1.00. We are strongly recommending that states give thoughtful consideration of applying threshold levels to amounts that are clearly not cost

to pursue. Please refer to Section F, Page 18 of the Medicaid Drug Rebate Operational Training Guide for tolerance thresholds for invoicing rebates and Section I for interest thresholds.

o Failure to Pay Rebates and/or Interest

Generally, manufacturers are paying rebates timely, displaying good faith efforts to resolve disputes and paying interest on untimely payments. However, we are aware of a few manufacturers that unreasonably and routinely withhold rebate payments or fail to pay interest. We will continue our attempts to address these isolated problems with the specific manufacturers through our dispute resolution efforts but in those situations where we are unsuccessful, we will be contacting appropriate manufacturer officials to address ongoing problems. It is not our intention to terminate manufacturers from the program but we are resolved to ensure compliance with the terms of the rebate agreement. We are committed to assisting states and manufacturers resolve disputes but it is discouraging to find a few manufacturers failing to demonstrate a willingness to comply with the responsibilities of the rebate agreement. Particularly disturbing is situations where, through our dispute resolution meetings, a manufacturer and state come to agreement on specific issues then, subsequently, a manufacturer fails to fulfill those agreements. We will aggressively pursue resolution in these cases and consider termination if warranted.

o States' Refusal to Review Data or Resolve Disputes

It has been alleged that at least one state has adamantly refused to review any disputed items identified by manufacturers; rather, the state threatens prior authorization of the manufacturer's products unless full rebates are paid without discussion or review of potential utilization errors. While 100% accuracy is a desirable goal for state utilization, our extensive experience in dispute resolution clearly indicates that such perfection is unlikely absent foolproof edits, the verifiable impossibility of pharmacy mis-coding or rounding errors, or the absolute elimination of human error. That's why we encourage a mutual exchange of information and open lines of communication to reasonably identify possible errors, correct them and settle disputes. We will be contacting this state to identify any potential problems and to assist it in establishing an effective dispute resolution process.

o Resource Limitations

Please be cognizant of the resource limitations facing states and manufacturers to varying degrees and the budget limitations on HCFA, which present challenges to timely resolution of disputes. It is not possible for HCFA to simultaneously conduct meetings with all states and manufacturers, nor is it reasonable for a state to expect that all manufacturers resolve all disputes with that particular state first, or vice versa.

Additionally, experience has shown that effective dispute resolution is most likely accomplished when sufficient advance planning occurs. To that end, we intend on formulating an ambitious but manageable schedule of Dispute Resolution Project (DRP) meetings for 1998 as outlined in the following item. The DRP to date has demonstrated that when manufacturers and states have a clear understanding as to the specific dispute issues to be discussed at the meetings, there is increased potential for reaching resolution. With effective advance planning, all parties will be better prepared for substantial progress in resolving disputes.

o Future Dispute Resolution Initiatives

Budget permitting, we plan to continue the DRP in 1998. Since 1994, we have been successful in assisting states and manufacturers resolve over $190 million in rebate disputes through the DRP. Current plans for 1998 include the continuation of DRP meetings in the Western and Southern Consortia, the implementation of DRP meetings in the Midwest Consortium and possibly the resumption of meetings for the Northeast Consortium states. Also, for states not able to participate in the consortia DRP meetings, we are considering individual state meetings or smaller groups of state meetings as budget limitations permit. We will be coordinating the scheduling of the DRP meetings with the consortia and regional office drug rebate coordinators who will subsequently contact individual states and manufacturers. We expect to announce the meeting schedules for the rest of FY 1998 by the end of December. States and manufacturers are encouraged to strongly consider attending the DRP meetings and to continue open communication with each other in pursuit of dispute resolution.

Please contact the DRP coordinators if you have any questions on any dispute related issue. Mike Keogh may be reached at (410) 786-5910 and Vince Powell may be reached at (410) 786-3314. You may also fax any questions to their attention at (410) 786-0390.

DRUG LABELERS

New Labelers

Horus Therapeutics (Labeler Code 59229) is to be reinstated into the program effective October 1, 1997. Pricing and rebate functions for their drug products will be administered by Monarch Pharmaceuticals until further notice.

The following labelers entered into drug rebate agreements with an effective date of participation in the rebate program of October 1, 1997:

Evans Medical (Labeler Code 19650); and

Hi-Tech Pharmacal Co., Inc. (Labeler Code 60569).

EXHIBIT 7

December 11, 1998

MEDICAID DRUG REBATE PROGRAM RELEASE #86

TODAY'S NEWS

for State Medicaid Directors

IMPORTANT NOTICE

MEETING SCHEDULE - DISPUTE RESOLUTION PROJECT

We are announcing our FY 99 schedule for the Dispute Resolution Project (DRP) national meetings to be held in the Western Consortium in Denver. These meetings are a continuation of the highly successful DRP national meetings held in Denver last September. The attached form provides the specific dates and instructions for States and manufacturers interested in participating. Please read the information. As was the case in September, these meetings are open to ***ALL*** States and manufacturers.

Given the enthusiastic support of Western Consortium leadership and in light of probable budgetary constraints, we have decided that Denver will continue to be the site of our national DRP meetings throughout 1999 and we will concentrate our dispute resolution efforts at these meetings. Due to limited resources and time concerns, there is only a slight possibility that we may schedule other meetings at other dates and locations during 1999; ***thus, we strongly encourage all States and manufacturers to participate in the Denver meetings.***

As was the case during our September national meetings, adequate DRP staff and facilities from both our Denver and Dallas Regional Offices, as well as HCFA Central Office, will be available to conduct concurrent meetings throughout the three, one-week sessions. In order for us to effectively plan the meetings, it is imperative that you respond per the attached form as soon as possible.

WITHHOLDING PAYMENT ON UNDISPUTED REBATES AND THE INAPPROPRIATE IMPOSITION OF INTEREST

It has come to our attention through our DRP meetings that while most manufacturers and States are committed to resolving disputes in an equitable and timely manner, two disturbing problems have surfaced. In both cases, the problems may be isolated and we are taking steps to address the issues with those manufacturers and States individually; however, we believe it appropriate to clarify the two separate issues with the following examples at this time to all States and manufacturers.

Situation A. -- A manufacturer disputes rebates on a portion of the units invoiced but withholds payment on the entire invoice.

A manufacturer is required to pay rebates timely or notify the State of those units and amounts specifically disputed. We believe it is unreasonable and a violation of the rebate agreement for a manufacturer to withhold payment on any unit not in dispute.

Situation B. - - A State invoices a manufacturer for 1,000 units; the manufacturer timely pays rebates for 600 units and disputes 400 units. Through dispute resolution efforts, it is ultimately agreed that the 400 units disputed should be reduced to 100 units.

The manufacturer must pay rebates on the additional 100 units plus the applicable interest. It is not acceptable for the manufacturer in this situation to take interest credit on the 300 unit reduction since the manufacturer did not pay rebates on those units initially.

Please refer to the Topical Index for previous releases containing guidance on interest.

We trust this information clarifies these two situations and, as we indicated earlier, we are taking steps to address these issues individually with the manufacturers and States involved. If any State or manufacturer encounters similar situations or any obstacles to resolving disputes, we remind you to contact the appropriate regional office drug rebate coordinator. If further assistance is required, please contact either of the DRP coordinators, Mike Keogh at 410-786-5910 or Vince Powell at 410-786-3314.

TRAINING GUIDE CORRECTION

Page F6, updated in Release Number 85, contained a print error. Please use the attached page F6 as the revised page for 11/98.

CORRECTIONS FOR 9/8/98 and 11/9/98 T-BILL RATES

The T-bill rates previously given for 9/8/98 and 11/9/98 are incorrect. The correct rates are 4.917 and 4.584, respectively.

NEW LABELERS

The following labelers have entered into drug rebate agreements and are joining the rebate program effective April 1, 1999:

CollaGenex Pharmaceuticals, Inc. (Labeler Code 27280); and

Capellon Pharmaceuticals (Labeler Code 64543).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period September 15, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member listed in section "O" of the Medicaid Drug Rebate Operational Training Guide.

Sally K. Richardson

Director

4 Attachments

cc:

All State Drug Rebate Technical Contacts

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

DRUG REBATE PROGRAM

DISPUTE RESOLUTION PROJECT (DRP)

1999 NATIONAL MEETINGS

Please check ***below*** **ANY AND ALL** dates you would like to attend at the 1999 National DRP meetings which will all be held in Denver. States **AND** labelers, please FAX your completed form to Diane Dunstan only.

DATE: April 26 to 30 ____

DATE: June 14 to 18 ____

DATE: Sept 13 to 17 ____

NAME: _____STATE/LBR CODE:_____

PHONE: _____ FAX: _____

OF REPS. EXPECTED TO ATTEND: _____

FAX to: Diane Dunstan (303) 844-3753 ***AS SOON AS POSSIBLE***

For **STATES ONLY**: What labelers would you be interested in visiting with?

_____

_____

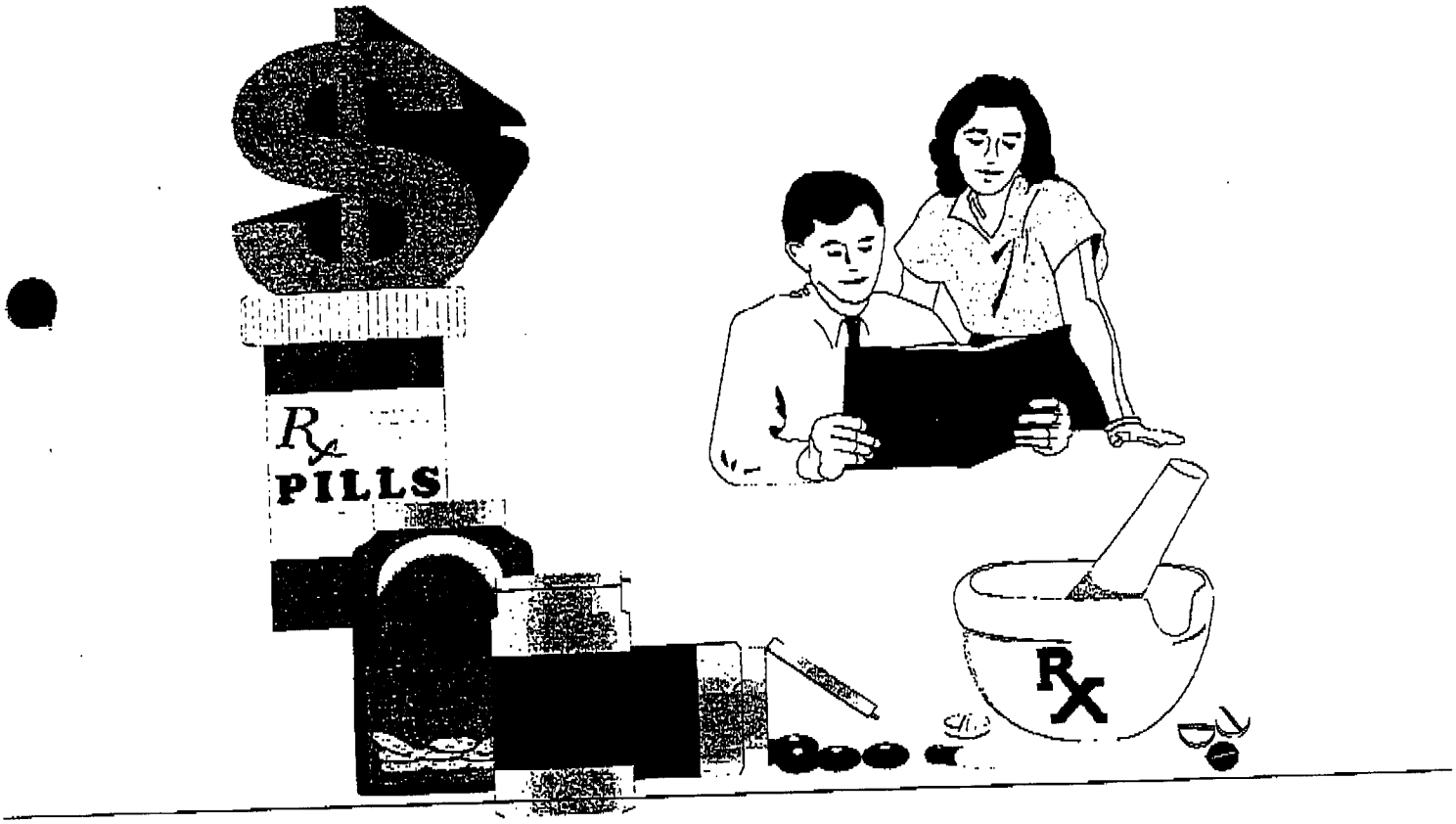
For **LABELERS ONLY**: What States would you be interested in visiting with?

_____

_____

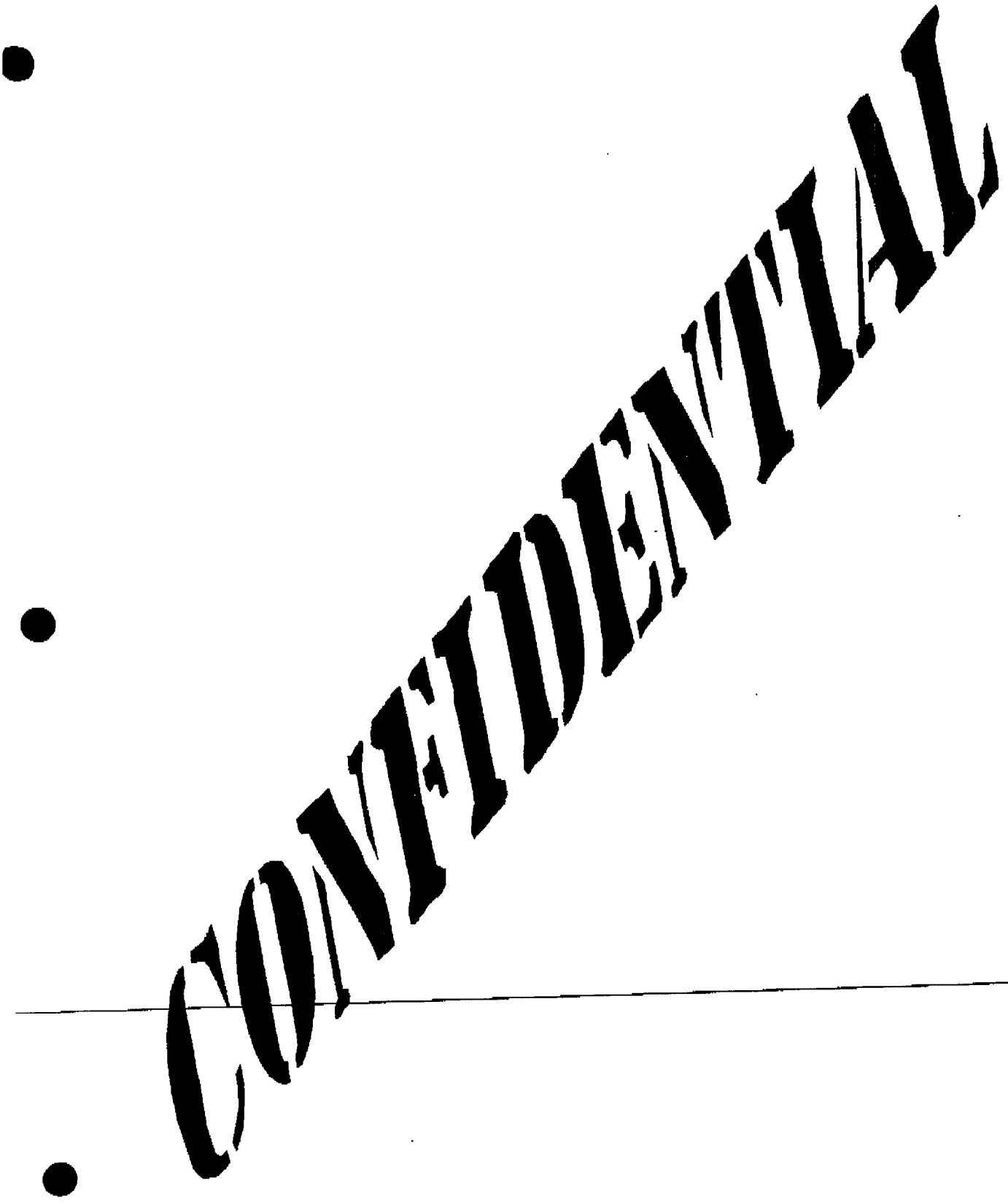
EXHIBIT 8

MEDICAID DRUG REBATE OPERATIONAL TRAINING GUIDE



Prepared By:
CMS's Center for Medicaid and State Operations
Finance, Systems and Quality Group – Division of State Systems

September 2001


CONFIDENTIAL

CONFIDENTIALITY

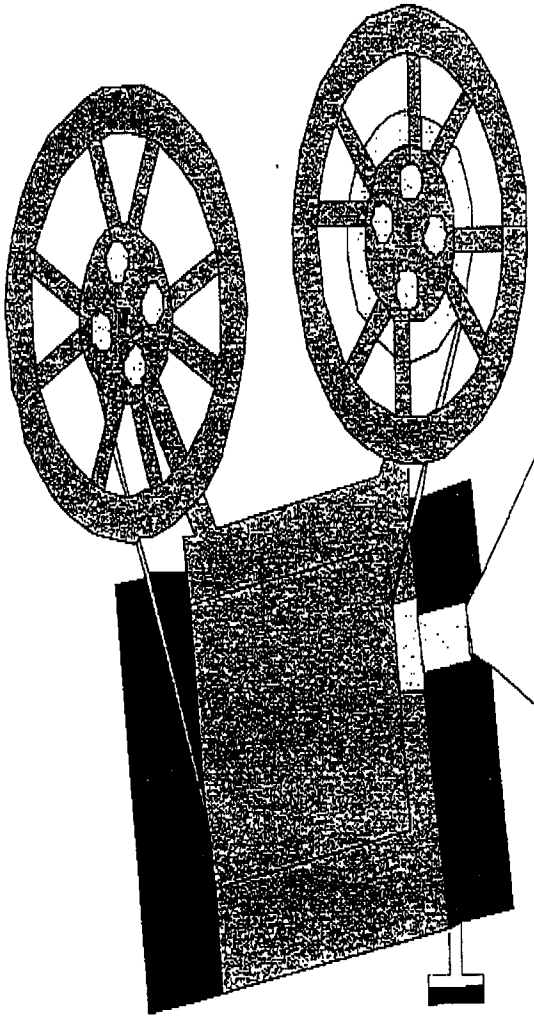
Section 1927(b)(3)(D) of the Act and the Medicaid Drug Rebate Agreement state that information disclosed by labelers is confidential and shall not be disclosed in a form which discloses the identity of a specific labeler, or prices charged by labelers. This provision covers all states as well as CMS.

Although the statute provides for three exceptions to the disclosure of labeler/prices, data related to prices are generally subject to both privacy and trade secret restrictions and are not released by CMS and must not be released by states. The pricing data CMS receives is held in the strictest confidence and maintained only on CMS's master files. CMS sends URAs to states, but actual pricing data goes no farther than CMS.

The three exceptions to data disclosure are data that are: 1) public knowledge; 2) legally obtainable from other sources; or, 3) not considered confidential. CMS complies with these requests for data.

In accordance with the Drug Rebate Agreement, labelers will hold state Medicaid utilization information confidential. This includes additional information on original data received and any information acquired during audits of such data. Except where otherwise specified in the Act or the agreement, the labeler will observe state confidentiality statutes, regulations, and other properly promulgated policy.

PROGRAM OVERVIEW



PROGRAM SYSTEM AND GENERAL REPORTING

This section describes the drug rebate program data system and gives a general outline of the data flow of a quarterly rebate cycle, from labelers to CMS, CMS to states, states to labelers/CMS, and finally, labeler rebate payments to states.

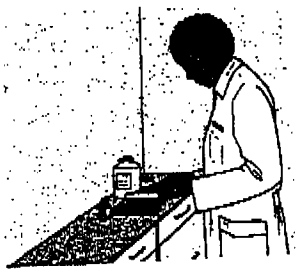
CMS's data system for the drug rebate program is called the Medicaid Drug Rebate Initiative (MDRI) master file. The general setup of the MDRI system begins with Baseline data generated by the labelers. Baseline data consists of the "profile" of each product that has a National Drug Code (NDC) sent to CMS using a specific record layout and containing specific data. DESI Indicator, Therapeutic Equivalency, Unit Type, and Drug Category are just a few examples of the data required to establish an NDC on the MDRI system. (See section F for the detailed record layout and data elements required.)

Baseline data for all covered outpatient drugs are submitted initially within 30 days after the end of the quarter of the new labeler's optional start date. (CMS provides new labelers with both the optional and mandatory starting date for their participation in the program.) From this point on, when submitting quarterly pricing data, a labeler **MUST** also include Baseline data for every new NDC that has a Market Date in the reporting quarter. For example, if a product is entering the market on 11-05-01, the Baseline data **MUST** be included in the 01-4 quarterly pricing data submission, due to CMS before the end of January, 2002.

Once a labeler is participating in the program, current quarter pricing data, along with prior quarter updates and additions are due to CMS within 30 days after the end of each calendar quarter.

CMS processes the quarterly data and sends edit reports to labelers for data rejected by the system. If labelers can correct information shown on the edit report and return the data to CMS before the system is shut down for rebate calculations, the corrected data will be entered and included in that quarter's unit rebate calculations. (Edit reports are discussed in detail in section G.)

The MDRI system shutdown occurs within 45 days after the quarter ends. The URAs are generated and tape/data cartridges are created and mailed to all 50 states and the District of Columbia. The states should update their master drug rebate files to reflect information contained on the CMS tape, verify URA adjustment data with labelers' rebate payments, and incorporate all current quarter URAs into their file for billing purposes. In addition to URA data, the CMS tape contains an updated labeler contact name and address file. States should also overlay their labeler contact files each quarter to reflect this updated information.



Within 15 days after receiving the URA data tape from CMS, states must submit invoices to each labeler for any NDCs the state reimbursed a pharmacy for during the past quarter. States also must submit utilization adjustment records (unit changes) for past quarters where units billed are determined to be incorrect.

State invoicing to labelers can be submitted using several media. It is the state's option whether to submit invoices in paper form, by diskette, or electronically. CMS does not mandate the reporting media for invoices, however, the collection of the invoice data and its reporting format (data fields/elements) are mandated. (See State Invoice, Section F.)

For all invoicing, each state must generate a separate record for each NDC billed to the labelers and submit a tape to CMS containing all utilization for the quarter. That is, whatever the state invoices to labelers each quarter, that same information MUST be submitted to CMS. CMS uses the utilization data received on the states' tapes for internal studies as well as reports to the Congress, the Inspector General, and Government Accounting Office.

Within 38 days after the postmark of the state invoice, labelers are required to pay rebates to states for all invoiced NDCs, except for those which are disputed by the labeler. All disputes must be initiated based on units and must be for "reasonable" cause. The dispute can involve the entire number of units per NDC, or any portion thereof. (The Dispute Resolution Program is discussed in section K of this guide.)

Payment to the states using the correct rebate amount is, ultimately, the responsibility of the labeler; thus, many calculate and pay states based on their unit rebate amounts rather than the rebate amount calculated by CMS. If an invoiced URA is different from the one calculated by the labeler, it is up to the labeler to research the difference and determine if it calculated the URA incorrectly or if pricing data sent to CMS was not correct. If the labeler's URA calculation is inaccurate, the labeler is to correct its baseline/pricing data and pay the state(s) using the CMS URA. If the labeler URA is correct, the labeler must change the URA and total amount due on the invoice, include a ROSI form, send the documentation to the state and send pricing or price-related data corrections to CMS. CMS will generate PPA records for the corrected NDC and include the PPAs on the next quarterly URA tape. These PPAs are used by the state to verify that the labeler's URA is correct.

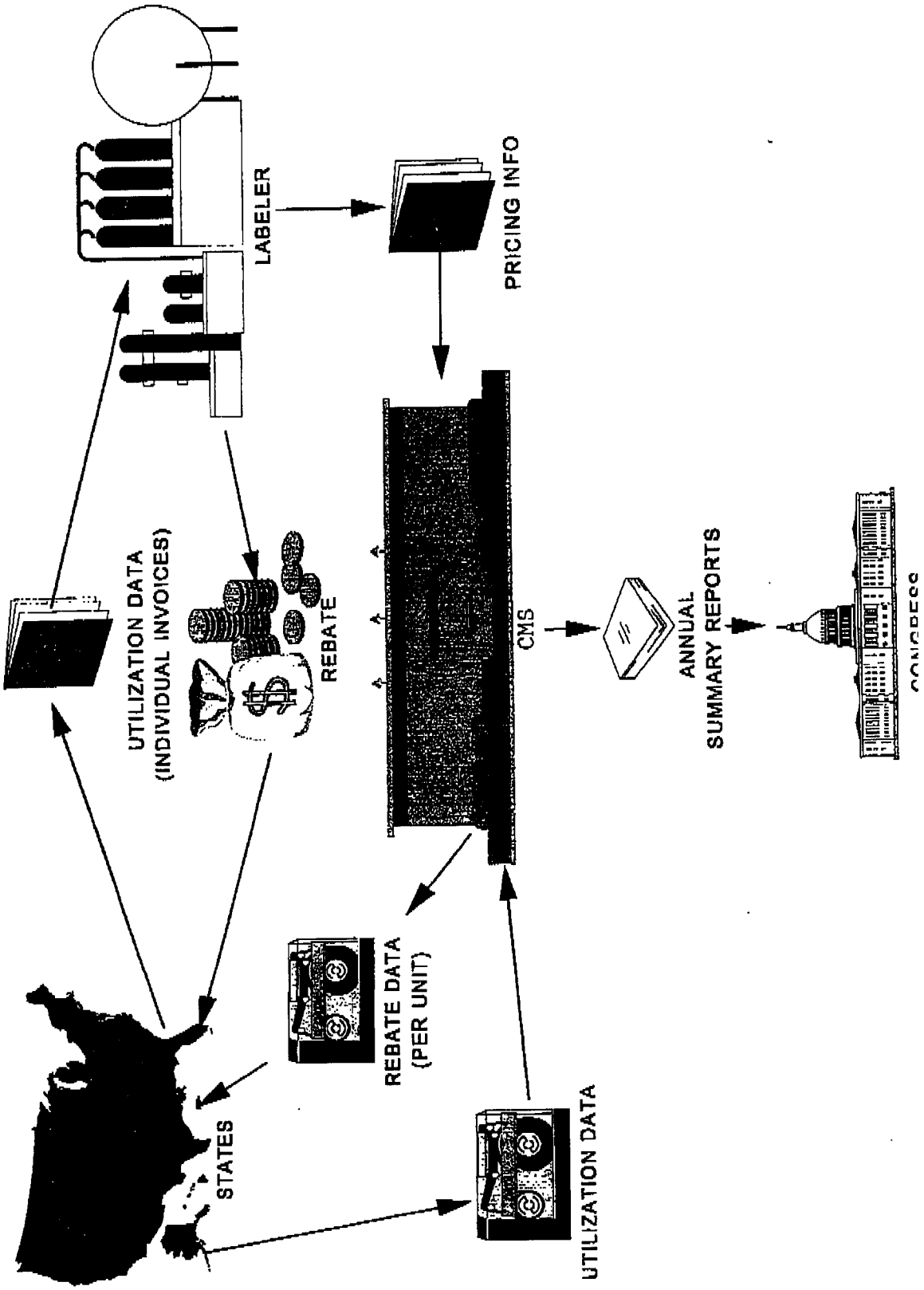
Additionally, under the following specific condition, labelers are allowed to correct utilization on an invoice. If an invoice arrives and an apparent error in utilization of an NDC is reported, the labeler is instructed to contact the rebate contact at the state and discuss the findings. If, after examination, the state analyst agrees with the labeler's findings, the labeler can change the utilization, calculate total rebate due and include a ROSI with payment to the state.

In addition to product data reporting, labelers are required to report administrative data to CMS. This data consists of contact individuals involved in the program and a data transmission option form. The latter of these requirements (form 367c) is generally considered a one-time submittal, but can be updated as the need arises. Historically, the labeler contact data is ever-changing and labelers are required to submit these changes on the OMB approved form 367a. It is imperative that ALL changes (area code,

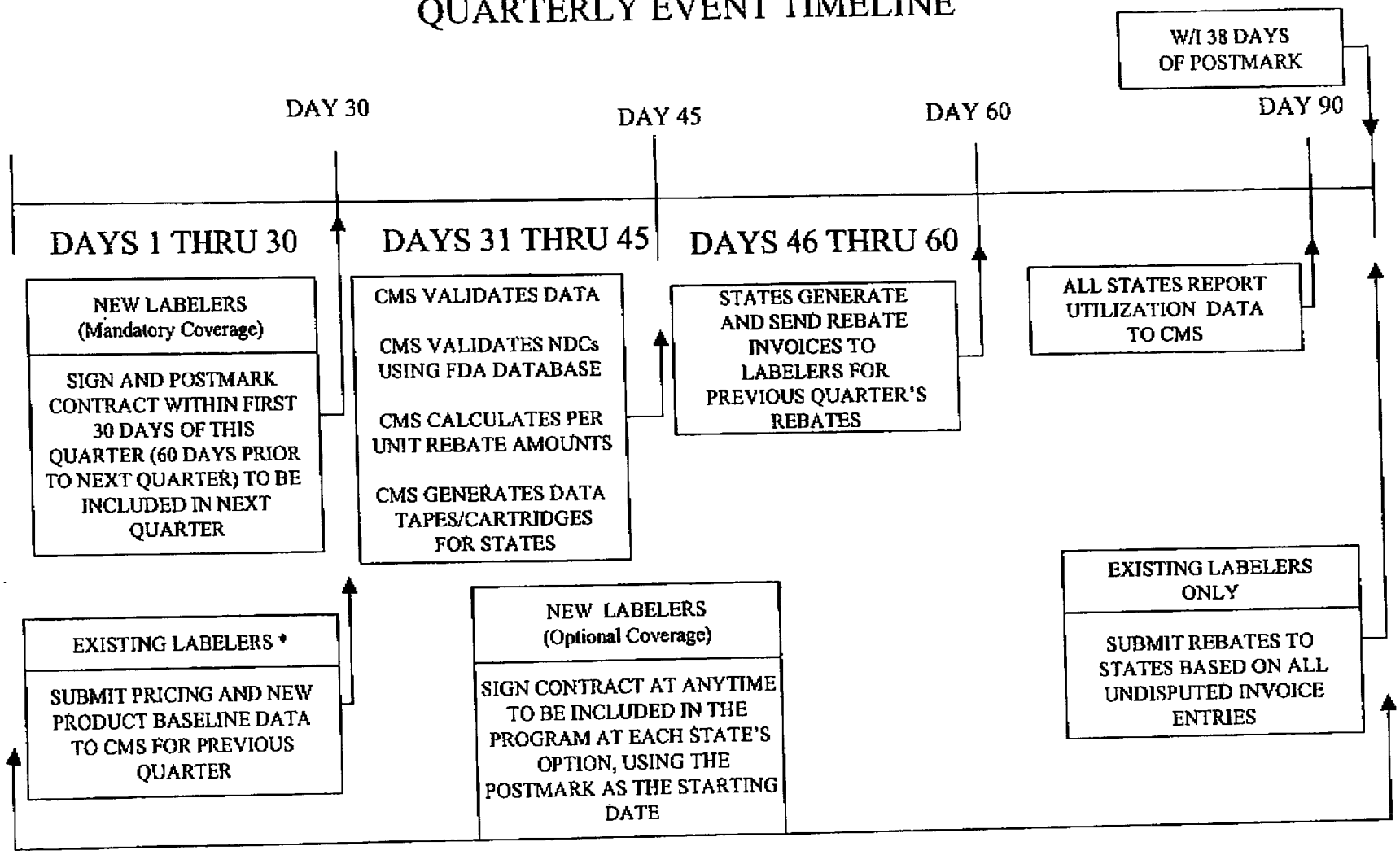
phone number, extension, name, etc.) are reported to CMS as soon as possible after the change occurs. If not, all the states and CMS will have incorrect contact data which could cause problems in the quarterly process.

States also are required to report administrative data to CMS consisting of contact individuals for technical, policy, and invoice matters. Form 368 was developed and approved by OMB for this purpose. As with the labelers, states are also encouraged to report ALL contact changes immediately to avoid problems and delays in the quarterly process.

MEDICAID DRUG REBATE PROGRAM



MEDICAID DRUG REBATE PROGRAM
QUARTERLY EVENT TIMELINE



* EXISTING LABELERS INCLUDES ALL NEW LABELERS WITH AN AGREEMENT POSTMARK DATE ANYTIME IN THE LAST QUARTER